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Introduction

The forthcoming sections of the synopsis throw light on-Health scenario in India including reproductive health, highlights the significance of health insurance, throws light on infertility problems in India and their solutions in the form of Assisted Reproductive Technologies, the challenges faced by couples in getting these treatments and finally how insurance companies can bring a solution to these problems.

The Health Scenario

Health is an indispensable marker of human development. Health stands in India have enhanced significantly since independence. Life span has dramatically increased since independence, infant mortality Rate has fallen,

malaria has been contained, small pox and guinea worm have been totally eradicated and leprosy and polio are nearing elimination. We have made further advances into rural areas with centered plans like the National Rural Health Mission and have even begun a plan for medical coverage for the poor people too. In spite of these accomplishments, the health administrations that India gives to her people keeps on being a long way from adequate and compares rather inadequately with even Asian neighbors like Sri Lanka and China.

One fifth of the world's share of illnesses is in India, there are huge territorial differences in health standards in the nation and tremendous holes in medicinal services framework, in rural areas. One of the key reasons is the low government spending . India spends just 3.9 % of GDP on health which is less when compared to its other developed and developing counterparts (refer the table below)

Table - Health expenditure as a percentage of GDP in select countries

Name of the country	Percentage of GDP spent towards Health Expenditure
United States	17.9
United Kingdom	9.3
Germany	11.1
Japan	9.3
China	5.2
Nepal	5.4
India	3.9
Korea	7.2
Srilanka	3.4
Pakistan	2.5

Source: UNDP, Human Development Report 2013

Status of Health Insurance in India

In a developing nation like India, many find the medical treatments to be unaffordable. Health Insurance was propelled in 1986 in India and from that point forward the business has developed essentially. As per the World Bank report , by 2010, more than 25% of India's populace should have had some type of medical coverage, however, as of 2017 the penetration of health insurance is only 20% (Source - EY report on Global analysis of health insurance in India) . There are private insurance providers alongside government sponsored health insurance providers. As of not long ago, to enhance the mindfulness and decrease the hesitation for purchasing medical coverage, the General Insurance Corporation of India and the Insurance Regulatory and Development Authority (IRDA) had launched an awareness campaign for all segments of the population. Health protection in India normally pays for just inpatient hospitalization and for treatment at doctor's facilities in India. Outpatient administrations were not payable until recently, but now few private players have started paying for outpatient too. The most popular health policy for many years was Mediclaim. In Year 2000, Government of India liberalized insurance and permitted private players into the market. The entry of private players in India saw the presentation of numerous imaginative plans such as family floater plans, top-up plans, critical illness plans, hospital cash and top up policies.

Common health insurance plans include Critical illness plans, Disease specific plans, Maternity health insurance plans, Senior citizen health plans etc.

Reproductive Health

Inside the structure of the World Health Organization's (WHO) meaning of reproductive health as a condition of complete physical, mental and social well-being, and not merely the absence of disease or infirmity, reproductive health, or sexual health/hygiene, addresses the reproductive processes, functions and system at all stages of life. Reproductive health implies that people are able to have a responsible, satisfying and safer sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so. Further it also means that men and women ought to be informed of and to have access to safe, effective, affordable and acceptable methods of birth control; also access to appropriate health care services of sexual, reproductive medicine and implementation of health education programs to stress the importance of women to go safely through pregnancy and childbirth could provide couples with the best chance of having a healthy infant. People do confront disparities in reproductive health services. Disparities differ in light of financial status, instruction level, age, ethnicity, religion, and resources accessible in their condition. It is feasible for instance, that low pay people do not have the resources for proper health services and the knowledge to comprehend what is fitting for keeping up reproductive health.

Infertility

Infertility affects approximately 15% of couples of reproductive age.Infertility is a serious problem in India, both among men and women. It has been a common myth, especially in the Indian society that infertility is always due to the problems in women. With rising awareness, however, this myth is slowly disappearing as more and more men are opening themselves up to being tested and understanding the repercussions of ignoring it however, it is equally due among both the sexes. Statistics say that infertility conditions account for nearly 40% respectively among men and women. A couple who fails to achieve conception even after a year of unprotected intercourse is considered infertile. While 40-50 percent of the recorded cases of infertility

are as a result of female bodily conditions, around 20 percent include abnormal sperm conditions and the rest are classified as unidentified factors.

Growing Infertility

Approximately 22-33 million couples in the reproductive age have been suffering from infertility in 2015. In the age bracket of 20-44 years 10% -15% of couples in India have been suffering from infertility. Total Fertility rate is the average number of children born to a woman in her reproductive span. Total fertility rate has fallen from 5.7 in the year 1961 to 2.3 in the year 2015 (India) and from 3.9 in the 1990s to 1.9 in 2013 (Karnataka).

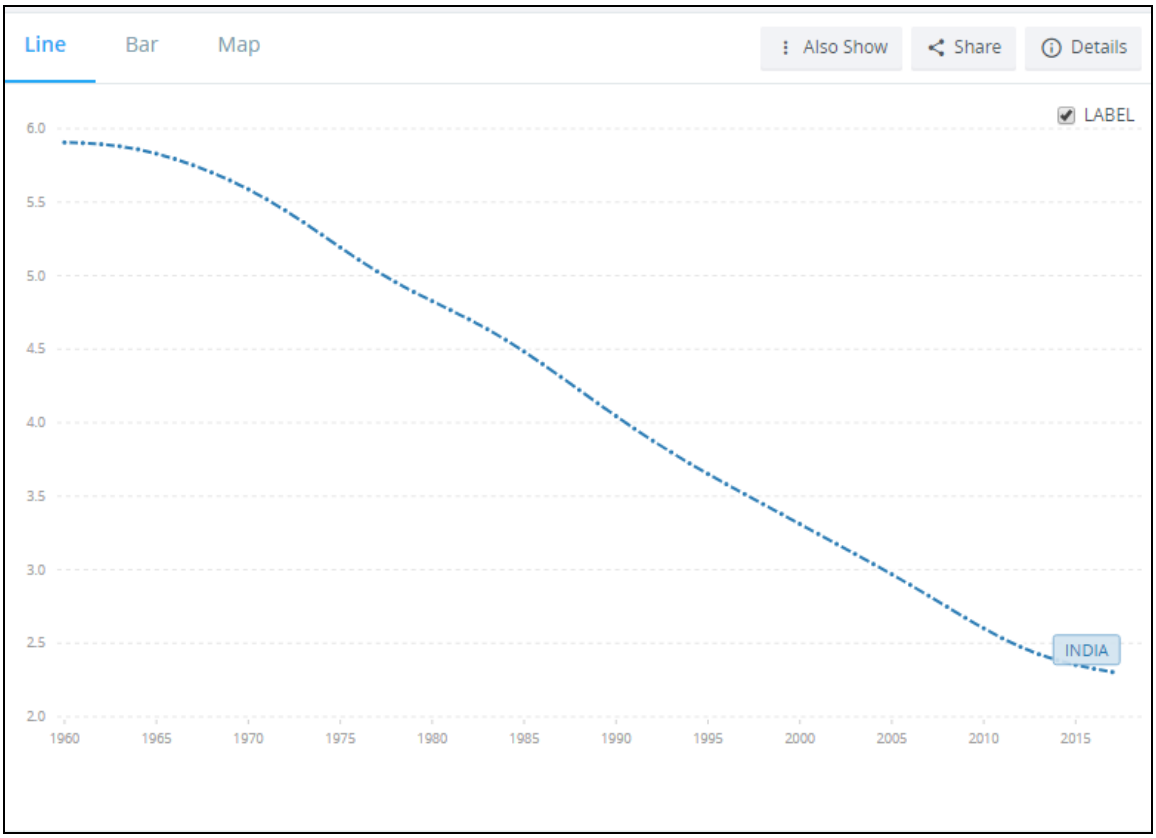


Fig 1 TFR from 1960 to 2015 - Steep decline from 5.7 to 2.4 Source - World Bank Data

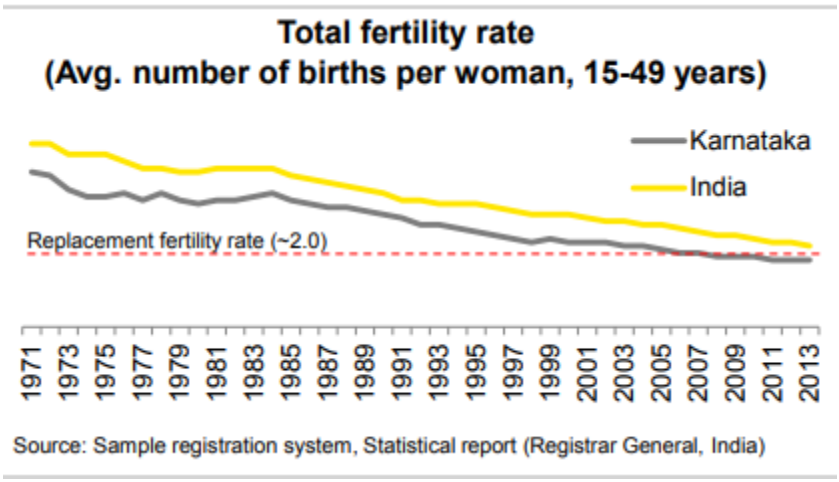


Fig 2 TFR from 3.9 to 1.9 Karnataka : (Source Sample registration System report)

According to another report published in 2014 the rates have dropped even further. Following is a glimpse of the falling rates.

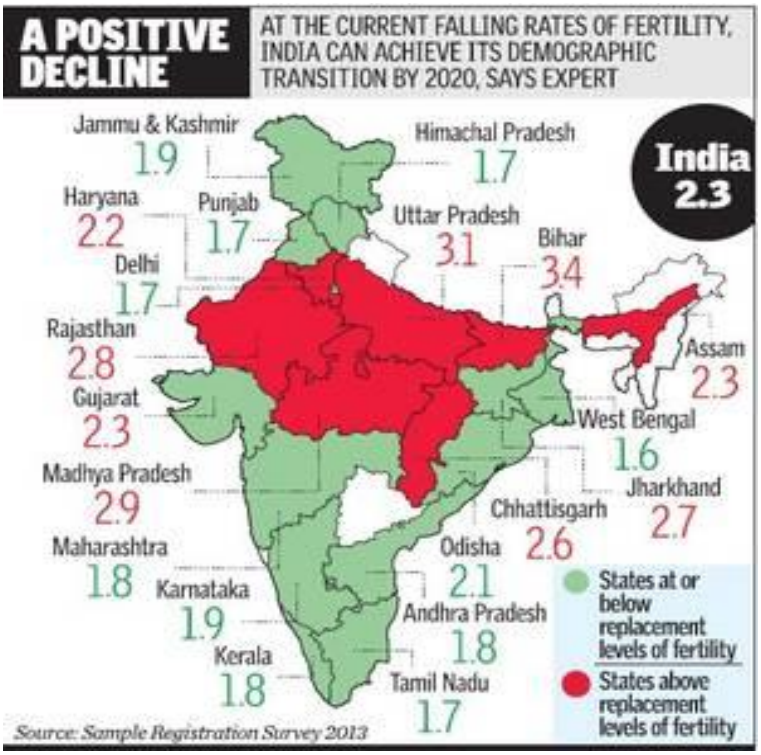


Fig 3 State wise TFR transition: (source- Sample Registration Survey 2013)

Fortunately, India has been one of the pioneers in treating Infertility through an array of Assisted Reproductive treatments. Infact, the second IVF child in the world was born in Calcutta , India. ART such as IVF, IUI, ZIFT, ICSI, Surrogacy and opting for a gestationtal barrier is getting immensely popular in India

Background of the study

The following provides a brief overview of the Assisted Reproductive Treatments available in India, the costs of these treatments, hurdles in acquiring these treatments and the insurance products designed in foreign countries to cover these costs.

Assisted Reproductive Treatments (ART)

ART or assisted reproductive technology involves specialized fertility treatments where both sperms and eggs are treated, rather, fertilized in-vitro usually in a Petri dish in laboratory. The woman's eggs are removed from the ovaries and are fertilized by male's sperms in laboratory. The zygote is then placed back into the woman's uterus for implantation and further development. Some of the assisted reproductive treatments are -

- **IVF or in vitro fertilization:** IVF refers to fertilization that happens outside the body of the woman. This is the most common type of ART. IVF is mostly done in case of blockage of woman's fallopian tube or when the sperm count of husband is low.

- **IUI or Intrauterine insemination :** UI or intrauterine insemination or the artificial insemination is the process involving insertion of 'specially treated sperms' in the woman's uterus. The woman is often cured with special medicines before undergoing IUI in order to stimulate the process of ovulation. IUI is done commonly for treating male infertility and cases of unexplained infertility.

- **ZIFT or zygote intra-fallopian transfer or tubal embryo transfer:** ZIFT is quite identical to IVF except for the fact that in ZIFT the embryo at a very young stage are transferred into the fallopian tube instead of the woman's uterus

- **IFT or gamete intra-fallopian transfer:** This type of ART includes transfer of sperms and eggs in the woman's fallopian tube so that instead of external environment, the fertilization occurs in the woman's own body.

- **ICSI or intra-cytoplasmic sperm injection:** This technique is done for those infertile couples where there is some problem with male fertility or who have a history of failed IVF attempts. In ICSI a viable single sperm is injected into the mature egg and the egg is fertilized.

- **Surrogacy:** If a female is not having viable and healthy eggs and is unable to conceive, she might opt for surrogacy. In surrogacy second or donor woman legally agrees to become pregnant with the sperm of the first woman's husband. Genetically speaking the born child belongs to the male partner and the surrogate mother. The surrogate mother is given heavy amount of compensation for bringing the child in the world.

- **Opting For A Gestational Carrier:** If a woman has some health issue sand is unable to carry fetus in her uterus or has ovaries but no uterus, then the available option is to seek the help of a gestational carrier. The egg of the original mother is fertilized by her husband's sperms and the embryo is then placed inside the uterus of the carrier woman.

Assisted Reproductive Technology Centers

India performs ~ 100,000 ART cycles annually, with a significant concentration of ART cycles being performed in metro cities. The infertility market is highly fragmented with very few players performing more than 1000 cycles per annum across major metros. There is a significant geographic skew in access, with more than 50% of the cycles performed across the top eight metros. The top eight metro cities account for around 55% of ART cycles performed. Poor geographic distribution of infertility treatment facilities highlights the difficulty in accessing treatment options faced by patients.

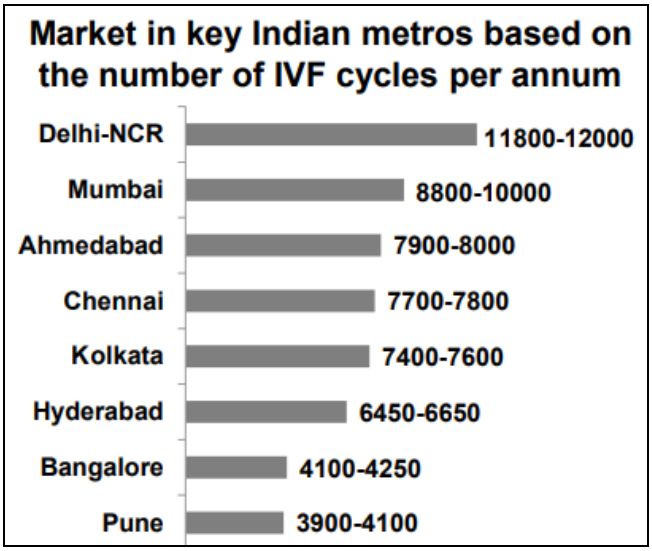
ART centers may be broadly dissected into four groups performing >1000, 500-1000, 100-499 and 1000 cycles per annum.

Table -Number of ART clinics in the metropolitan cities

City	No. Of ART Clinics
Delhi	60
Mumbai	70
Hyderabad	18
Chennai	25
Bangalore	20

ART clinics in India ; Source National Assisted Reproductive Technology Registry of India

Each metropolitan city has a market of minimum of 3000 cycles to a maximum of 12000 cycles Following is an example of IVF as one of the ART treatments.



Distribution of cycles in Market; Source National Assisted Reproductive Technology Registry of India

Cost of ART Treatment- A Barrier

A large international study demonstrated that Indians seem to have a high propensity to seek fertility treatment, but awareness is a major barrier. Need for parenthood (the importance of having children) is greatest in India and lowest in Japan. Social status of parenthood is more influential in India and China, but is less valued in countries with a high level of economic development. Awareness of fertility problems is lowest in India compared to other countries. Increasing awareness of infertility is a key imperative in India, as many couples do not suspect a potential problem when in fact, they should already be seeking treatment, which further reduces their chances of conceiving, over time.

While the cost of ART treatment in India is 3-4 times lower than in the US, treatment is unaffordable for 80% of population due to low average household income levels with 21% of households (52.6 million households) having an annual income >INR 200,000 . The average cost of each ART cycle ranges from 1.5 to 2.5 lakhs. If the ART treatment is not successful during the first cycle then new cycles have to be performed. Majority of public and private insurance programs do not cover infertility, excluding ESI (Employee State Insurance) Corporation, which provides ART treatment facilities to insured persons.

Insurance cover for ART treatments

Countries like Belgium, Germany, France, Great Britain, Israel, Italy, Netherlands, Austria, Russia, Spain, Sweden and Turkey provide ART coverage. They infact have National Health Insurance coverage. In places like USA and Canada it is provided by Insurance companies. The employers and Insurance companies join hands to indemnify the insured. Thus, receiving ART is comparatively easy. However, countries like India, China and Japan don't offer coverage.

Statement of the Problem

Progeny is every man's aspiration. In India, this is a matter of great sensitivity and an inability can contribute to serious psychological , social and emotional distress. It is quite disturbing to see the increasing number of infertility cases in India. Even worse is the fact, that , although treatments are available , many couples are not able to receive it. On one side while we have solutions in the form of Assisted reproductive technologies , not every couple is able to make use of it. While in other countries, either the Government or the private insurance players cover these costs, in India, it is absolutely not covered. Infertile couples face lots of challenges in getting treatment - long waiting hours, incessant doctor visits and emotional pain , but worse than all is the inability to afford the treatment. Each cycle costs around 1.5 to 2.5 lakhs. Success is not guranteed in one cycle, hence multiple cycles are required. An average Indian cannot afford multiple cycles and hence they discontinue the treatment. With that their dream of giving birth to a child is also lost leading them to a life of despair. When infertility affects a couple, it affects a women more, especially if the she and the society comes to know that she is the reason for childlessness. She goes through stress and depression. The other problem is inorder to increase the success of the cycle, doctors upon request of patients inject multiple embryos which results in Higher Order Deliveries, cut short the treatments or find alternative means to reduce costs so as to make it affordable for the patient. This may have adverse effects on a patient. It is high time, that India , just like any other developing country , finds a solution to this problem. If Insurance companies agree to indemnify infertility treatments, many childless couples can make use of the treatments. However, as we can see from the above literature, Insurers have their own arguments for not including infertility treatments. Their apprehensions and hesitations are not known clearly, neither is it known what exactly a doctor or patient requires from an insurance cover. There is a need to bring all the three stakeholders together, understand the requirements and find a solution to the problem. Perhaps, a framework which aims to help the insurance companies in covering infertility treatments by considering the propositions and perceptions of Patients, Clinics and Insurers will solve the existing issue.

Need For Study

Assisted Reproductive treatments are a boon to the mankind. Suffering of human beings due to childlessness is one of the most painful one. Be it due to natural physiological dysfunction or due to accidental physiological dysfunction, the suffering is immense. Progeny is every man's right and dream. With the advent of Assisted Reproductive treatments the hope among the childless couples soar and the fulfillment and gratification of them becoming parents is joyous. However, for them it comes with a cost. The treatments are very expensive and not everyone can afford it. The feeling of not being able to give birth to child just because financially one cannot afford it makes the pain even worse. Infertile couples go through depression and it affects their work, their relationships and their day today activities. Although, on the outer surface , all seems to be well, it is not.

Insurance as a financial product is very powerful and is useful in undertaking of risks by capitalizing on the principle diversing of risk among many . Health Insurance products are very popular and developed in India. But one area where insurance is still not developed is in India is in providing coverage for Assisted Reproductive treatments. The niche and not well understood area is not developed due to lack of research .

The motivation and inspiration of the study comes from the feeling that all people , rich or poor should be able to afford infertility treatments in India, just like everyone else in the world is able to .

Review of Literature

The existing literature are varied in nature- Some of the studies talk about the stigma faced by childless women in the society, the challenges faced by patients, the financial worries of couples not being able to afford the treatments, the repercussions of cutting treatment costs on mankind, whether insurance cover should be given, if not , why shouldn't it be given, how can insurance covers help the patients and challenges and concerns with regard to assisted reproductive treatments.

Discussion on literature

The social stigma

Infertility hurts both men and women. But women more so. Women continue to face the social stigma of not having a child. Being childless hurts most of the women, be it in any part of the world. Women particularly go through stress , anxiety and depression when they face infertility issues Donkar (2007), Widge (2002), Reissman (2000) .

Arguments for and against covering infertility treatments

Arguments against Assisted Reproductive Technology insurance coverage are many. The fact that infertility is not a medical problem and it is a social problem is one such argument. It is not a medical necessity. For some treatment to be covered there has to be enough data to prove that the treatment is effective. Predominantly all ART treatments are experimental and thus insurance companies cannot cover the same. Principally insurance companies do not cover experimental treatments. Beh (1998) While some say that Medically ART is not necessary it cannot be completely overruled. At some point of time in life of a woman ART may be a medical necessity. For instance, for a women who is suffering from depression of not having a child, ART becomes a medical necessity. However, for women who already have a family, this may not be a medical necessity. The strongest of all arguments is of a social nature. If more number of couples go for ART treatments (assuming ART comes under Insurance coverage), the number of adoptions in the country will fall. Adoption is a very noble act of giving a

family to an orphan while at the same time giving a child to a childless parent. The counter argument to this argument is that Adoption is a very expensive and difficult process, also the burden of adoption should not be put on the infertile couples. Chen (2010)The argument that ART is not a treatment as all treatments leads to cure, whereas ART does not cure Infertility is also negated . Insurance companies do cover pacemaker and artificial limbs treatments similar to ART treatments, even they dont cure the ailments. Hughes (2001) One good argument in favor of providing insurance coverage for ART treatments is that money alone should not be the determinant for becoming a parent. To become a parent is every man and women's birth right and no one should be deprived of that. Shanley (2009) .

Exploring the possibilities of an Insurance cover

If at all Insurance companies start covering ART treatments, one of the conditions could be age limit. Carter(2013) If Insurance coverage is given it may affect the usage of services, the pattern of fertility services and it may also affect the outcomes. (Jain) Whether ART insurance cover can be clubbed with other maternity benefit driven policies is a question. On one side the couples who never will use ART will pay premium for those who use expensive treatments, on the other side, couples who will never deliver a child shall pay for deliveries of all other fertile couples. Some employers are ready to cover these treatment costs as they wish to motivate their employees, hold on loyal employees. However, they wish to cover only for employees who make requests to cover these costs. Isaacs(2008). Theoretically, any insurance company providing maternity benefits should provide the ART cover

Repercussions of lack of education about infertility treatments and not providing insurance cover

Since there is no insurance coverage for ART treatments and each cycle is expensive, doctors on the request of patients for transferring multiple embryos. This sometimes results into multiple pregnancies. Thus, the effect of lack of insurance coverage can be correlated to multiple pregnancies. Reynolds(2003) Providing insurance cover for ART treatment also reduces cost per live birth (since only one embryo will be

transferred during one cylce) Pepperstraten(2008). Poor women are given awareness about Contraceptives whilst the rich get more awareness about Assisted Reproductive technologies . King(1997) . In countries where Insurance was provided initially for ART treatments and later it was deinsured in such places there is a reduction in ART M.Giacomini(2000). Australia could bring down the multiple birth rate by using ART techniques aided by Public funding and proper clinical guideline usage while giving treatments. Chambers(2012) Once the ART cycle fails they dont go back again for treatment as another cycle means again spending lot of money . They stop the treatment as they are not able to financially afford it. Goldfarb(1997) . Usually the women who go for ART treatment are older women from the middle to upper strata of the society. While some go for ART treatment after few years of marriage, some of them wait for a long time..Young couples can be successful within 4 years of treatment. However, the treatment should not be discontinued in the middle. If Insurance coverage is provided , they would surely continue. Lack of funding has a direct relationship with Higher order deliveries sometimes as high as triplets and quadreplets. (Lande)

Heavy Costs- A burden on infertile couples ; Yet less success rates

The success rates of IVF range from 30 to 35% but lots of couples are led to believe that the success rates are more than 50%. (Sanchita Sharma and Annona Dutt, Hindustan Times, July 2018) The treatments are less likely to be successful in contexts where there is a lack of technical expertise and shortage of supplies resulting in safety issues for women, increase in multiple pregnancies, low birth weight babies, perinatal mortality, risks of ovarian hyperstimulation, and high costs Inhorn(2003) The treatments are so expensive that patients sell of their property, Jewelry or they take bank loans. Costs are not standardized and differ from clinic to clinic. Costs vary with investments in infrastructure. Providers feel that the high costs of these treatments are an impediment to infertility treatment. Costs can be lesser if the patients are ready to wait but they are so desperate and vulnerable that treatments become expensive, for eg instead of going for multiple cycles of IUI, directly going for IVF. Widge et al (2009) Couple’s income and accessibility of treatment decide the patterns of treatment-seeking. Sometimes due to high

costs couples resort to unqualified practitioners or sometimes leave the treatment and go midway. Singh et al(1996) •

No guidelines- No monitoring

There are people who go for treatments 4 months after marriage. There are no set guidelines for these treatments. There are no records, monitoring or regulation. There should be a robust national registry and a body like Human Fertilization and Embryology Authority in the UK. Doctors may be tampering the figures for showing more success rates. Widge (2009) In order to minimize the risk of multiple pregnancies, a process should be devised to determine the optimum number of embryos transferred in a woman. In countries where IVF is publically funded or funded through insurance companies, there are proper regulations with regard to transferring multiple embryos. Guidelines by American Society of Reproductive Medicine clearly recommends transferring of one or two embryos at cleavage stage or single blastocyst in a woman <35 years of age. But in India, as each cycle would cost them more money, they go for multiple embryo transfer just to be on a safer side. This results in Multiple pregnancies. Bhattacharya et al (2014) .In an elaborate study undertaken by two researchers on ART clinics through a questionnaire, lots of it was found that Patients do not understand the biological processes involved in giving birth to a child. They don't understand the treatments. They don't ask proper questions to doctors and they are not able to ask anything about success rates, ovulation and any complications for the child. People don't even know the difference between ICSI and IVF. They think that ICSI is to be done if you want a male child. Since many ART practitioners don't have time appropriate counseling is not often given to patients. Widge et al (2009) A well-known concern is a fact that practitioners offer IVF to patients instead of IUI. They have their own explanations for the same. Patients are so desperate and vulnerable that they do not want to face the uncertain outcomes of an IUI, they want to go with IVF as it is comparatively more successful. From the Doctors perspective, an IVF provides a more controlled environment and so it is advantageous to monitor. However, IUI as first-line treatment should be offered to most patients, while funding agencies and stakeholders need to be urgently informed of the cost-benefit in offering IUI. Fertility clinics, IVF interest

groups, and regulatory bodies should amend their patient information and guidance to state that IUI should be the first line treatment and that IVF should be offered only when essential. Bahadur & Homburg (2019) Not all the doctors practicing in India are thoroughly trained in ART. ART is not included in curricula of medical colleges and there is no recognized certificate course, super-specialty for ART or regular medical education training. Most of them attend workshops conducted outside India. These workshops are range from 4 days to 6 months. Sometimes they own a diploma and sometimes it just mentions workshop attended on the certificate. In cases of male infertility, the man has to be also guided through initial workup and in case of any male related infertility factors which detected the case has to be referred to a male infertility specialist. The findings from the study show that eighteen percent of couples underwent costly ART prior to an inexpensive male workup (Balasubramanian et al., 2019)

Evils of Infertility Treatments- PGD , Sex selection and Commercial Surrogacy

Preimplantation genetic diagnosis (PGD) a technique invented in the 1900s is the selective process undertaken during the in vitro fertilization (IVF) procedure to detect genetic abnormalities. This is done so as to implant only those embryos which do not have any genetic abnormalities. Though this technique can reduce the burden on the economy by eliminating diseases such as consanguinity and genetic disorders such as thalessmia but it can be misused for preimplantation sex selection Kar et al(2018) .Commercial Surrogacy in India is the biggest concern. Did the country do right by legalizing Surrogacy is a question which many researchers, policymakers, and human rights activists ask. On one side it has enabled poor women to manage their meals and on the other side, it has opened the door for institutionalized exploitation up to the extent of isking their lives and dignity on the other hand. Instead of performing its constitutional duties towards the poor, the state by legalizing CS is encouraging poor women to rent out their wombs to fulfill their basic needs. This raises a serious question mark on the moral and legal foundation of the country. Both mother and child are treated as a commodity. Kumar (2019) India is the most preferred destination for Surrogacy. But there is no data on the number of clinics and the number of surrogacies. Surrogacy has become a business. There are many people who get benefited by this business especially the

fertility clinics. Saravanan(2018). Sex selection techniques for family planning are existing in India. The market for sex selection in India is popular because of the high desire for a son. There are medicines used for sex selection which has lots of side effects including multiple pregnancies, birth defects and still births. The science which was used to control diseases is being used for social reasons Rai etal (2018). Couples in India want a balanced family of one boy and one girl and so this technique is prevalent. Malpani et al. (2002) There are health hazards while treating the patient for subfertility. Abdominal cocoon syndrome a rare phenomenon was observed in a 30 years lady admitted to Katmandu Medical College. She was suspected of ovarian hyperstimulation syndrome following IVF -Embryo transfer. Doctors did a first line conservative treatment and then finally she was treated surgically and her pregnancy was terminated. Pandey et all (2018) There can be accountability issues from the Doctors side too. Patients keep consulting various doctors, the number ranges anywhere between 2 to 14 doctors. Every time the diagnosis and treatment start once again. They go to homeopaths and quacks. Gynecologists were criticized by ART providers for delayed referrals leading to repeated investigations. Widge et al (2009). In a report by Sama (a Not for profit organization which works for rights of women), it shows that the Surrogates have absolutely no say in the choice of technologies to be used, procedures she would go through, money she would get for surrogacy, living conditions of the child during the carrying period and so no. Commissioning parents prefer surrogate to stay in a very conducive environment. All others like the Commissioning parents, doctors, agents play a prominent role. Surrogates feel lonely and feel they are not able to participate in the whole process due to so many channels of communication often in an hierarchical form. They can't read and write English. The only thing told to them is they don't have any rights over the child once the child is born. Major portion of their payment depends on the happening of the birth of a live child.

Research Gap and Lack of evidence

The existing literature provides a rich base of arguments for and against insurance coverage for assisted reproductive technologies treatment and also throws light on the benefits of covering these treatments to combat infertility problems. There are numerous challenges faced by couples in getting an ART treatment done. One among them is affordability. There is very less literature found in the Indian context in this regard.Studies done so far are either from the medical perspective trying to analyze the biological causes for infertility , from the commercial perspective of how Assisted Reproductive treatments have been helping infertile couples while gaining popularity in the Indian market or from the philosophical perspective of whether Assisted reproductive treatments should be encouraged.There are very less studies which have combined causes and concerns and have arrived with suggestions for policy makers so that the boon of ART does not become a bane. Though, India is one of the pioneers in ART , Indians are not able to access these treatments properly. The clinics seem to be catering only the few , who can afford the same. There is very less literature to show what problems people are facing with regard to availability and what problems doctors face in making the treatments available to population.

Although, in India this problem has been acknowledged , there are not enough articles to show the solutions for this problem. Again, ART clinics play an important role in the whole process. Yet, there is very less literature which talks about their opinions.

Specifically less evidence could be found to answer the following questions -

- Why Indian Insurer's hesitate to provide insurance coverage for ART ,
- What are the opinions of treatment providers (Clinics) with regard to insurance coverage
- What do the beneficiaries feel about the lack of such an insurance product and the formation of such an insurance product..why do they need it, how much does it cost them, what do they really spend , how can insurance help them

- Is there any solution to this problem ? Can Government and Insurance companies together do something?

The study aims to bridge this knowledge gap in the existing literature.

Methodology

This section starts with the statement of the problem, underlying ontological and epistemological assumptions of this study, why this study is oriented towards a particular paradigm, what approaches have been used for each research question, which methodology has been followed for collection of data , the types of participants , the procedure followed for analysis and interpretation and finally the findings.

Paradigm- Constructivist- Interpretivist

A Constructivist Interpretivist paradigm forms the base of the study. On this particular study not much research has been done and not many explanations and solutions are found, knowledge could be gained by interacting with people who have experienced certain phenomenon such as infertility (patients) , with people who have implemented few processes and have administered and facilitated people who are going through infertility (Medical Practitioners) , the providers of insurance who ultimately would be designing the policie (Insurance experts) and by assimilating knowledge on how other countries are successful in implementing ART policies.

A deeper understanding of how policies can be effectively framed and detailed descriptions of emotions and vulnerabilities of patients - their needs, their challenges, financial problems and Doctors dilemmas in treating ART patients, and Insurers apprehensions of not designing an exclusive product has been interpreted. Using these three stake holders thoughts and challenges the attempt has been made to come up with feasible framework which ultimately can be turned into an useful product to help the mankind. Ironically, this sounds like a Transformative paradigm also , however since there is no change programme which is designed taking the help of participants , even though the research positively advocates the change to happen and hence it is purely a Constructivist Interpretivist paradigm.

Purpose of the study and Scope

To gain a deeper understanding of the current situation in India with regard to Assisted reproductive technology treatment insurance policies and to understand the

challenges faced by all the three stake holders namely - Patients, Doctors and Insurers and subsequently devise a framework so as to enable Insurance providers and Government to come up with policies and schemes to help patients get treated with less financial burden.

Scope of the Framework

It is limited to designing covers for Women facing infertility issues (due to female infertility factor). Male infertility factor and coverage of male is out of the scope of study.

Central Research Question

How to devise policies and schemes so as to ease the financial burden of Patients going through Assisted Reproductive Technology treatments, to help Doctors administer the treatments peacefully (keeping the cost related anxieties at bay) , to help Insurance companies to come up with products that are feasible and sustainable and to help Government to build mechanisms that ultimately benefit patients suffering from Infertility ?

Diagrammatic representation of how the answer to the central research question has been arrived by developing research questions , why was there a need to gather secondary data even before starting the primary research has been explained below .

Only after understanding the components of framework for insurance policies prevailing outside india and understanding the causes of infertility in India, the components of Framework for the Indian market could be built.

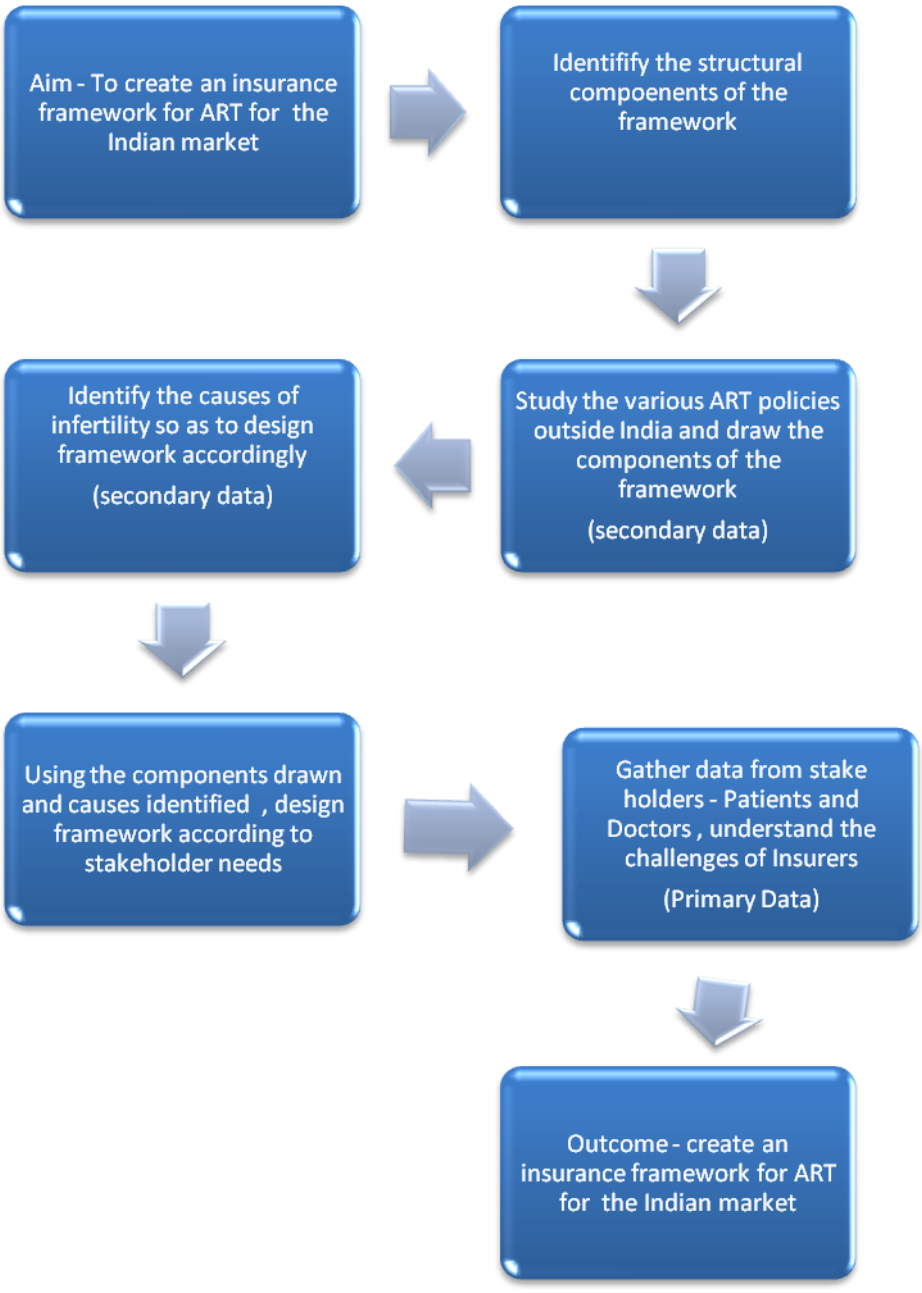

Aim - To create an insurance framework for ART for the Indian market
Identifify the structural compoenents of the framework
Study the various ART policies outside India and draw the components of the framework
(secondary data)
Identify the causes of infertility so as to design framework accordingly
(secondary data)
Using the components drawn and causes identified , design framework according to stakeholder needs
Gather data from stake holders - Patients and Doctors , understand the challenges of Insurers
(Primary Data)
Outcome - create an insurance framework for ART for the Indian market

Figure- Schematic representation of achieving the answer for central research question using both secondary and primary data

Research Questions/Approaches/Methodology

The following table throws light on the research questions, underlying approaches and methodologies that will be used.

Research Questions	***RQ1 How are artificial reproductive treatment insurance policies framed world wide ?*** ***RQ2 What are the causes for Infertility ?***
Approach	**Qualitative Content Analysis (for both research questions 1 &2)** It is referred as "a research method for subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns" (***Hsieh & Shannon, 2005, p. 1278)*** As ***Schreirer (2012***) rightly puts, the data reduction is achieved by limiting "analysis to those aspects that are relevant with a view to the research question. Initial literature review threw a plethora of Artificial reproductive treatment procedure guidelines in the international context. Many insurance companies in the west have drafted many policies either with the Government financing model, company financing model or a purely insurance model. Each model's policy has its own good and bad. There is a particular rationale for inserting a condition , exclusion and cover. Similarly, there are many sources which talk about causes for infertility from many dimensions. For instance there are videos by medical practitioners, research papers in medicine journals, Conference proceedings and talks by infertility experts. To select the information required for this study is a tedious task and requires weeding out of unwanted information and carefully selecting

	only the information required. Qualitative content analysis approach allows limiting analysis to relevant aspects with view to the research question.
Method	**RQ 1.** Systematic Review of literature using Gough (2007) model has been conducted. Under the chapter of Research Question number 1 a detailed description of inclusion and exclusion criteria , sources and screening of articles has been mentioned. After selecting the relevant articles, pertinent information was extracted . ART public funding frameworks of 20 countries have been analysed. Hospitals and Clinics providing insurance covers have also been analysed . And analysis of private insurance frameworks namely- Hong Kong Health Insurance- CCW Global, Cigna, Nippon Insurance, Kaiser Permanente, AETNA has been done. **RQ 2**. Content analysis using articles published in Pub Med Database particularly in the Indian context has been done. There were no dates kept in mind while doing research due to limited data available. All articles were extracted for the study with few inclusion criterias mentioned in detail under the Chapter of Research Question 2.
Results and Discussion	**RQ 1** The aim of the first research question was to understand how a policy is framed. Thus after reviewing all frameworks (Government funding, hospitals and private) a list of components that could be used to prepare a framework and a list of coverages, conditions and exclusions have been prepared. **This was later used as a base to interview the doctors to understand its fitment in the our country** . **RQ2** The aim of the second research question was to make a comprehensive list of the causes leading to infertility. All the articles reviewed has been presented in a tabular format and the finally the causes have been listed. This list has been used to prepare the final framework indicating the cases which could pose a physical hazard to the insured. The list also forms the base for reproductive diseases cover in the framework. **These causes form the backbone of the framework, because only after understanding the causes and the section of the society that requires the help of framework, the**

	design of the framework has been made. The analysis process in qualitative content analysis comprises selecting the unit of analysis, categorizing and finding themes from categories **Following were the themes extracted -** *Causes of infertility in women in India, Framing of Insurance Policies*
Research Question	***RQ 3 How patients experience the ART process emotionally and financially?***
Approach	**Qualitative Content Analysis** In the words of ***Sandelowski (2000)*** Qualitative content analysis are data-derived and the least interpretative compared to other approaches to qualitative analysis because "there is no mandate to re-present the data in any other terms but their own"
Method (Data Collection - Source / Participants- Tool)	Interviews with patients going through infertility treatments were conducted with the help of a structured interview guide. Thirteen respondents were interviewed. All the interviews were done face to face only. Some interviews happened in a hospital setting and some at a convenient meeting place. Interviews were noted down and they were not audio recorded. The Interview guide is attached for reference in the Annexure. All patients filled the informed consent forms ,some signed, while few were reluctant to write their names. A renowned hospital in Bangalore provided a silent cabin to do few interviews with patients too. One in fifty patients agreed for the interview. Patients were first asked by the Researcher at the reception if they would like to be a part of the study while they are waiting for a turn . Of all the thirteen respondents , none of them were known to the researcher prior hand. Two respondents had discontinued the treatments after a long battle, and the others are still in the process of being treated. Detailed information about the respondents and interviews in provided the Chapter of RQ 3.

	Respondents were selected based on two things - Whether they have undergone or /are undergoing ART treatment and their ability to speak without any fear or emotional distress.
Results and Discussion	First the handwritten notes were typed in Ms. Word verbatim in a Question and Answer format. Thereafter, the common answers given by respondents to each question were noted down. Later all uncommon ones too were written down. The analysis chapter is arranged question wise. Each question has a section called 'Responses' which gives a glimpse of responses given and 'Excerpts' describing the verbatim responses, giving the reader a much clearer view of responses. After re reading the Results section and the transcripts again, Discussion was written Themes extracted were - **(Availability)** *Role of Education in getting treated* *Lack of Trust in hospitals - Low Success rates- High Costs and Fear of losing both Money and child* ***(Treatment)*** *Patients level of knowledge wrt treatments* *The treatment journey* *Wrong Diagnosis - Unnecessary IUI, waste of money and delay in the right treatment* *Battling with Anxiety and Depression* *Cost decides the treatment* *The feeling of No Money - No Child*
Research Question	***RQ4 How do medical practitioners administer the ART procedures?*** ***RQ5 What will be the effect of an insurance cover on the administration of the treatment?*** ***RQ6 What are the practitioners expectations of coverage from an ART insurance policy?***

Approach	Qualitative Content Analysis
Method (Data Collection - Source / Participants- Tool	Indepth face to face interviews were conducted with 13 doctors practicing ART Treatments. Out of that 10 doctors were okay with audio recording of interviews and three doctors were not okay with it. Three doctors were owners of hospitals themselves and other ten worked with renowned hospitals in Bangalore. They varied in the number of years of experience. However, all doctors had experience of a minimum of 8 years. Doctors with less than eight years of experience and who were not specialists in reproductive medicine were not be considered for the study. Directors and senior consultant doctors only were considered for the study. Junior consultant doctors were not a part of the study. The interviews were conducted with the help of a Interview guide (Refer Annexure) . The interviews were conducted in their hospital premises in their cabins itself. The approximate time per interview was 45 mins to 1 hour. Consent forms were not signed looking at the nature of the audience. Names of hospitals and doctors have been masked through out the study. To get a clarity on the covers, exclusions and treatment conditions, a need was felt to again meet the doctors and get help in putting the framework as per the indian needs. Of the 13 doctors , three doctors volunteered to help. They evaluated the Covers, Conditions and Exclusions and gave their comments. Refer Annexure The whole exercise of evaluating took them on an average of 2 to 2.5 hours.
Results and Discussion	First the recorded audios were typed in Ms. Word verbatim in a Question and Answer format. Thereafter, the common answers given by respondents to each question were noted down. Later all uncommon ones too were written down. The analysis chapter is arranged question wise. Each question has a section called 'Responses' which gives a glimpse of responses given and 'Excerpts' describing the verbatim responses, giving the reader a much clearer view of responses. After re reading the Results section and the transcripts again, Discussion was written. **Of the coverages, exclusions and conditions that the three doctors had evaluated , the most common ones have been selected for the framework.**

	Medical Conditions for prescribing treatments have been identified All those tests/ diagnostic procedures/ treatments etc that a practitioner thinks should be covered have been identified. The common processes followed by Practioners for administering the ART treatments have been explained Indepth understanding of Practioner's view point of non availability of Insurance covers for infertility treatments have been described. A Rationale for covering infertility treatments from the practitioners point of view has been analysed. General framework of an insurance policy including an approximate Sum Insured has been created only because of the help of the doctor interviews. Following themes were extracted - **(Treatments)** *Starting the infertility treatment* *Process followed by doctors* *Consistency in procedures* *Financial worries come in between the treatment of patient* *Juggling to make the treatments affordable for the patients.* *Treating the poor*
Research Question 7	***RQ 7 How to put the drafted framework in to practice ?***
Approach	**Qualitative Content Analysis**
Method (Data Collection -Source / Participants- Tool	Indepth Interviews with 10 health insurance specialists were conducted with the help of an Interview guide **(Refer Annexure**) and the rough draft of the framework consisting of covers, exclusions and covers etc. All the ten of them had an experience of working with insurance industry for more than 15 years. They were a mix of employees working with Public sector, Private sector, T.P.A' s ,Brokers and regulatory bodies. Five interviews have been audio

	recorded and five could not be due to reluctance from the experts side in recording of audio .There was no consent form signed . The interviews were conducted at their residences. Three interviews were conducted in their offices in their chambers, the rest seven were conducted in their residence or at a convenient meeting point. Interviews lasted for a minimum of 1.5 hours. Few interviews went on for 2 hours too.
Results and Discussion	First the recorded audios / hand written notes were typed in Ms. Word verbatim in a Question and Answer format. Thereafter, the common answers given by respondents to each question were noted down. Later all uncommon ones too were written down. The analysis chapter is arranged question wise. Each question has a section called 'Responses' which gives a glimpse of responses given and 'Excerpts' describing the verbatim responses, giving the reader a much clearer view of responses. After re reading the Analysis section and the transcripts again, Findings were written **The findings helped in understanding the inhibitions and apprehensions from the point of view of insurers and designing a sustainable framework**. Following themes were extracted - ***(Insurance Coverage)*** *Framing of Insurance Policies* *Components of an Assisted Reproductive Technology Treatment Insurance Framework* *Practitioners'' expectations of coverage from an ART insurance policy?* *Bursting the myth - Infertility treatments are not covered in India by Insurance companies* *The rich gets the cover - The poor does not* *The status quo* *The reason for resistance in covering infertility treatments* *The way out - Solutions on designing a robust framework (Insurers perspective)*

	The draft of the framework has been presented to select experts who gave their valuable inputs , which has been incorporated in the framework.

Operational Definitions

1. Patient - Women who has been examined by the Doctor and has been suggested an infertility treatment due to female infertility factor

2. ART - Assisted Reproductive Treatment

3. Infertility clinics - Level 1, Level 2 and Level 3 clinics

4.Doctors - Only those practicing ART

5. Insurer - Both Public and Private sector

Results

Secondary Data

Part 1

Causes for Infertility in Indian Women

Why understand the main causes for infertility in Indian women?

With such varied school of thoughts, different regulatory systems, non standardized nationwide procedures, different stake holders with different needs and ideologies, the prerequisite is to understand the various dimensions to this issue and what researchers have to say with regard to those dimensions. Each country's demography is different. Thus causes for infertility in women would be different. To understand the status quo and suggest an insurance framework, one has to get to the grass root of the problem. India is a diverse country , with many few rich and many poor. One solution will not fit all. Besides knowing the root cause will help in finding the right solution. Another operational angle is that insurance companies need to know about the various physical hazards present in a particular risk coverage. Thus , there is a need to understand various causes of Infertility amongst women in India . A systematic review of literature has been undertaken and the findings have been presented. Gough's (2007) model for the stages of systematic review has been followed. Below the process has been explained of selecting the articles and extracted data has been presented.

Search Terms

Table - Terms used for giving search

Research question	Terms used for giving search
Main causes for infertility in women	' causes for infertility in women' 'factors affecting infertility in Indian women'

5.3 Search strategy and Study selection process

Search for published literature was performed through PubMed as it has a huge collection of data especially for infertility causes . The aim was to select only Indian articles whose studies were set in Indian context. There were no dates kept in mind while giving searches. All the articles available in the database in the Indian context were taken for the study. The inclusion and exclusion criteria is listed below

Table -Search Strategy

Feature	Inclusion Criteria	Exclusion Criteria
Type of publication	Peer reviewed Journals, Books, dissertations reports ,select newspapers	Magazines, Blogs, conference abstracts
Language of Publication	English	All other languages
Participant samples for Infertility causes	Indian Female	Indian Men, Foreign women, clinical trials on Mice and rats have not been considered.
Type of methodology	Clinical trials, Randomized trials, Interviews, Surveys, observation, Meta analysis, Content analysis of literature and study of narratives	-

5.4 Screening of Studies At the first level, the title and abstracts were screened to check if they meet the inclusion criteria. If the criteria's were met, they were selected for study.

5.5 Mode of Analysis , Discussion and Presentation of Evidence

Whilst reading the articles , the data regarding the Author name, Objectives of the study, methodology used, profile of participants, experiment/ research setting and findings of the study were drawn. The same has been presented in a tabular manner. A specimen snapshot has been provided below. In the Annexure F section, the full table has been appended.

	Article	Objective /Methods	Findings
1	Latent genital tuberculosis adversely affects the ovarian reserve in infertile women. *Kaur R Kaur T and Kaur A , 2018*	This prospective study from February 2013 to January 2016 compared 431 infertile women diagnosed with latent GTB (Group I) to 453 infertile women without latent GTB (Group II)	It was found that Latent genital tuberculosis adversely affects the ovarian reserve in infertile women. ***Genital Tuberculosis***

Part 2

Assisted reproductive treatment insurance policy frameworks outside India

Why study policy frameworks outside India

While designing any health Insurance framework, there are certain critical points to be kept in mind. Of course they may differ from one country to another due to demographic variations, but the hazards almost remain the same due to the nature of the subject matter. In order to design a framework for the Indian Insurance market, a thorough understanding of how ART policies are drafted across the world had to be gained. A systematic review of literature has been undertaken and the findings have been presented. Gough's (2007) model for the stages of systematic review has been followed.

The understanding gained through this exercise enabled the drafting of interview schedules to solicit information from Doctors .

6.2 The search

A systematic search of the Pubmed database using free text terms (see table below) was conducted to search for relevant articles. Using the exclusion and inclusion criteria (see below for full description of these criteria) those articles were identified that could potentially provide data to answer to the question. These targeted searches were supplemented with searches of Google and Google Scholar for published reports from various agencies that compile and publish data on assisted reproductive technologies. Number of hand searches from established journals in the field: Human Reproduction and Fertility and Sterility were also conducted. Bibliographies were also screened to retrieve papers for additional references.

Table – Search Criteria

Sr. No	Category	Search terms
1	Public Funding	Funding for Assisted Reproductive Treatments, Funding for Infertility treatments, Financing Assisted Reproductive treatments, Government support for Infertility treatments, Public funding for assisted reproductive treatments, Public financing for Assisted reproductive treatments
2	Clinics/Hospitals funding schemes	Fertility clinics offering assisted reproductive treatments, Funding by Infertility clinics
3	Private Insurers	Insurance companies providing Infertility treatments Funding infertility treatments Insurance policies for Infertility treatments

6.3 Inclusion And Exclusion Criteria

Papers that were published before 2007 were excluded as a part of the study. This decision was made on the grounds that the review was to produce an up-to-date picture of the existing insurance frameworks available with regard to assisted reproductive technology treatment and that data going back more than eight or nine years would yield little benefit. Newspaper articles and Blogs were not included. Articles in peer reviewed journals, Grey literature including reports by NGO's, Government agencies; Academicians were included for public funding. For the dimension of Clinics and hospitals, company websites and grey literature found were included. For the private insurers, grey literature in the form of brochures, reports and information from the company's websites were included.

6.4 Screening

After giving the preliminary search many articles were excluded as they did not fit the inclusion criteria. Not many duplicate sources were found. Of the ones which fitted the inclusion criteria , their abstracts were read and if it seemed that the document may consist answer for the research question, the article was downloaded for further research.

6.5 Sources Used

Please refer Annexure A (at the end of the synopsis document) for an exclusive list of sources used The tables indicate the final sources used to extract answers to research questions. The tables are presented in the same order of sources highlighting public funding art treatments, followed by sources used for drawing information about ART from clinics and hospitals that provide such financial products and finally private insurance companies who are into selling of infertility insurance products.

6.9 Results

The following paragraphs throw light on the Resultsdone on the extracted data separately for each dimension.

6.9.1 Resultsand Interpretation of Public Funding

To understand the most important components of an ART framework public funding frameworks of top 20 countries from Human Development Index has been considered. Using the research papers mentioned above common features have been drawn. The various type of assisted reproductive treatments covered by these countries have been mentioned in detail. The articles mention that public funding is covered assuming that the tests, diagnostic procedures, non surgical treatments, Infertility surgeries, and Artificial insemination will be covered. Conditions and Exclusions do not apply in the case of Public funding as the terms are of use only to Private insurers. Whether any additional services are covered or not is not available.

Below is a specimen snapshot depicting how comparison between countries has been presented . For full list refer Annexure B

ART PUBLIC FUNDING DETAILS FOR 20 COUNTRIES- Table 6.5

Sr. No	Name of the Country	Public Funding status	Number of Cycles	For which Medical Indication	Age of woman	Marital status	Number of Embryos allowed
1	**Norway**	Public funding partial	Max 3	No Information	<40 years	Married couples - Lesbians, singles not allowed	Single-embryo transfer preferred
2	**Switzerland**	No Public funding	No Public funding	No Public funding	No Public funding	No Public funding Stable	No Public funding
3	**Australia**	Partial	No limit	Infertility	No age limit	Relationship, Singles and Lesbians allowed	<35 1 embryo >38 2 embryos
		No		Only the cost			

6.9.2 Resultsof Clinics/Hospitals Funding

In order to understand how Clinics and Hospitals offer treatments with inbuilt financing options detailed Resultsof few select clinics which had information on their websites have been considered. The clinics are Create fertility, UK, Advanced Reproductive Care, Inc, Care Facility, and Fertility Associates. The basis for selecting these clinics was purely based on proper availability of content. These were the only hospitals which had information listed on their websites. A specimen for one hosptial has been presented below. The other hospitals information has been presented in Annexure C

Name of the Clinic	**Create Fertility, UK**
How it assists funding?	The clinic gives loans to patients who wish to undertake the treatment. For example if treatment cost is 9,984 . They take an initial deposit of 2,995, the loan amount is 6988 and the total repayment is 8372 which the patient can pay in monthly installments of 348 for 24 months or 582 for 12 months. This is for a treatment type of 3 cycles. For treatment type of 1 cycle the treatment cost comes to 3844 and the monthly installments for 24 months come to 134 and for 12 months 241.
What are the different packages?	The packages have basic coverage and additional charges for toppings Basic - Includes - monitoring scans, clinical advice, treatment plan consultation, egg collection, embryology, blastocyst culture, fresh embryo transfer, pregnancy blood test and early pregnancy scan.

	Toppings - with closed culture incubation (Embryoscope), IVM , HFEA cycle fee, blood tests (HIV 1, HIV 2, Hepatitis B core, Hepatitis B surface antigen, Hepatitis C, Luteinising Hormone, Oestradiol) and sedation by consultant anaesthetist., 3 egg collections, embryo freezing and storage for 12 months , pre-implantation genetic screening with Next Generation Sequencing (up to 4 embryos), 6 egg collections, 2 embryo transfers, ICSI Basic - Includes - monitoring scans, clinical advice, sperm preparation, insemination procedure, pregnancy blood test and early pregnancy scan. IUI - Toppings - 3 cycles, treatment plan consultation, Ovulation induction monitoring ,Embryo, Egg and Sperm Freezing, Frozen Embryo transfer procedure, FET after frozen egg thaw procedure with ICSI, Donor Sperm, Egg Donation, Egg Sharing and Surrogacy
Average desired age	No info found
Marital status	No info found
Min and Max cylces	1 cycle to 6 cycles
Number of embryos transferred	1 to 8 embryos
What are considered as advanced/ additional treatments?	PGS with Next Generation Sequencing, Pre-implantation Generation Sequencing (PGS) , Pre-implantation genetic diagnosis (PGD), Blastocyst culture ,IVM, Closed culture incubation (Embryoscope) ,Cyst aspiration, Trial embryo transfer,Hysteroscopy ,Transfer of sperm/eggs/embryos ,Surgical sperm aspiration ,Micro-TESE, DNA fragmentation for sperm sample, Sperm chromosome analysis, Combined DNA fragmentation and chromosome analysis, HFEA fee per cycle Sedation feee
Conditions	Not found
Exclusions	N/A

2.6.4 Resultsof Private Insurers

In order to understand how Private insurers across the world draft ART policies, the following information from the Insurance company's website was referred. Apart from this brochures available online were also used. The rationale for choosing a particular insurer was purely based on availability of completeness of information . Cigna, Nippon,

Kaiser and Aetna were the only Insurers from whom the information could be drawn online. No other insurance company displayed all the components online. Only the value proposition has been displayed with brief marketing aspects, but apart from these four companies , none of the insurance company displayed all components. A Specimen table of how Resultsand presentation of an Insurer's framework is shown below. Detailed information has been appended in the Annexure C section.

Pls note - AETNA has the widest and most exclusive framework and only excerpts from the framework has been presented below. All the components and structure of the framework has been presented below. Refer Annexure C for the full framework

NAME OF THE INSURANCE COMPANY	**AETNA**
DEFINITION OF INFERTILITY	Infertility is failure to conceive after 1 year of unprotected intercourse.
AGE	< less than 38
COVERAGE DETAILS	
Tests	Anti-sperm antibodies (e.g., immunobead or mixed antiglobulin method)
Diagnostic procedures	Ct or mr imaging
Non surgical treatments	Aromatase inhibitors and letrozole (femara)
Infertility surgery	Hysteroscopic adhesiolysis And many others
Assisted reproductive treatments	Ivf Ivf with embryo transfer
Additional services and artificial insemination	Gonadotropin releasing hormone (injectable medication)
Medical conditions	**Treatments permitted**
Hostile uterine cervix.	Intrauterine insemination with either husband’s or donor semen (IUI-H or IUI-D)

Irreversible pathology of the fallopian tubes, resulting from an inflammatory process or from previous surgery.	In vitro fertilization and embryo transfer (IVF-ET)
When the tubes are fine and fertilization can happen in the tubes	IVF–associated techniques Gamete Intrafallopian Tube Transfer (GIFT)
Male partner has Primary germ cell failure Inheritable genetic disorder	Embryo donation
Exclusions Test exclusions	Anti-mullerian hormone
Non surgical exclusions Artificial insemination treatment exclusion Treatment related exclusions	Leukocyte immunization (immunizing the female partner with the male partner's leukocytes) Double IUI Direct Intra-Peritoneal Insemination

Primary Data

Part 1

Patient Interviews

How patients experience the ART process emotionally and financially?

7.1 Profile of Respondents and Resultsof Interviews

The table on next page gives a gist of the status of all the thirteen patients. The table shows the year of marriage, when the first treatment started, number of clinics the patient had so far visited, tests conducted , past treatments received , current treatment going on and cause of infertility identified

Name & Age	**Year of Marr-iage**	**Year of 1st treatment**	**No Of Clinics visitied**	**Tests conducted**	**Past treatment**	**Current treatment**	**Cause of Infertility**
A , 27	2013	2014	3	Laproscopy, Haromone tests	Nil	IUI	Unable to explain
B, 41	2002	2012	2	Harmone tests	IVF with donor eggs	Harmone replacement and Androgen cycles , IVF with donor eggs	Poor quality/ quantity of eggs
P,29	2015	2017	2	No info	IUI (unsuccessful)	IVF (unsuccessful) and FET	Beta HCG cells very high quantity
J, 24	2016	2017	1	Blood test , Scan	Nil	Injections, IVF Diet and Yoga -	PCOD
C ,30	2013	2015	2	Blood test, HSG, Scan, Follicular count	Consulted homeopathy. No info available	No treatment as of now asked to reduce weight	PCOD
Z, 24	2017	2019	1	Blood tests, FSH , HSG, HIV tests etc, HMG	-	IVF	PCOD
S, 30	2014	2016	2	N/A	Some surgery (unable to tell)	IVF	Unable to answer
L, 29	2014	2015	3	Harmone injections	IUI (unsuccessful)	IVF	PCOD and Thyroid
V, 30	2010	2012	3	Blood test etc	IUI (unsuccessful)	IVF	Tuberculosis

G 36	2013	2008	2	All tests unable to explain	IUI IVF	Nil	Unexpl ained
M 31	2009	2012	2	Laproscopy	IUI	Nil	Tuberc ulosis
H	2014	2018	1	Blood test, Harmone tests	IUI	IUI	Unable to explain

Theme	*Sub Theme*
• Journey	Going to multiple Hospitals Probable Misdiagnosis High Uncertainty Cost as a deciding factor for the choice of treatment Delaying treatment Travel and Trust in doctors and lab
• Knowledge about treatment	
• Alternative medicine	
• Abiding by doctors advice	
• Costs	
• Emotional and Physical	
• Accumulate funds for treatment	
• Anticipation of future costs	
• What could have helped them?	
• Which stage insurance helps	

On their Journey

- **Going to multiple hospitals**

Most of the respondents said that they had taken treatments at multiple hospitals. Each clinic repeats the investigation from the scratch. For eg. In the case of respondent A a tube test was done twice - once in the old hospital and again in the current hospital. In the case of respondent B too same set of investigation was repeated in two different hospitals and they came to the same conclusion of going for donor eggs. In case of respondent S too although it is not clear whether it was the same set of diagnostic procedures done in both the places, but it is evident that doctors would have done the

basic tests before asking her to go for 'some surgery'. In this case , S could not even say what exactly the doctors had diagnosed her problem as. Looking at the cost of 1 lakh that she had spent, one may assume that Laproscopy would have been done in the first stage itself in the old hospital

*Around 2015 I realized the need for going for treatment. I am from Gulbarga , I consulted a doctor there. They detected PCOD and Thyroid. They gave me hormone injections for few months. Nothing worked. Later I consulted a Gynecologist in Bangalore and I did IUI there. Then she referred me to this hospital. In Feb 2019 I came here. Here they started with IVF. - L (*Personal Conversation)

- **Probable Misdiagnosis**

There could also be a case of misdiagnosis. For instance in case of respondent L she had tried the treatment in two different places before she got into the current hospital. The Gynecologist in the previous hospital had suggested IUI and she had done with no success , and now this hospital has put her on IVF whilst diagnosing her case as 'unexplained fertility' This raises a question as to why in the first place she was put through IUI. Is IUI the first port of call for some hospitals ? In the case of respondent V had timely diagnosis been done, the treatment would have been shortened. She was detected of Intestinal Tuberculosis in 2014 -2015 and finally she is now getting an IVF done in 2019. IUI was suggested even when the doctors found that there could be an issue with fallopian tubes due to Intestinal Tuberculosis. In this case , whether V was completely cured of tuberculosis while doctor suggested IUI is not known.

In 2012 I realised that there was an issue. Around 2014-2015 I went to a doctor in my town Mandya and they detected Intestinal Tuberculosis. Later I went to a Gynecologist and she suggested IUI and it was not successful. I spent 50 to 60 k. Later I went to a a big hospital in Mysore. The doctor there found that there could be a possible block in my tubes and she transferred my case to the main branch (the hospital where currently she is getting treated). The reason the case was transferred was because they

*dint have proper lab facilities(unlike here) . In this hospital they conducted a test and realized that tubes were not open. Doctors suggested to start IVF and so IVF started after 5 to 6 months. I took some time to decide if I finally wanted to go for IVF or not. December 2018 IVF started but till date no results. - (*Personal Conversation)

- **High Uncertainty**

All respondents felt that there is a great amount of uncertainty involved in these treatments. In case of P while everything seemed to be so proper and the IVF was declared successful , within weeks the pregnancy got aborted. In her own words ' it shook the doctors'

- **Cost as a deciding factor for the choice of treatment**

Although the initial impression one gets after hearing the respondents is that the treatment is based on diagnosis, however one particular case of respondent P shows a different aspect. While doctors initially suggested that she can go for the second round of IVF, she decides to go for an FET because the treatment has already costed her 6-7 lakhs and another round of IVF cycle means few more lakhs which could go into drain too. P knows that the chances of her getting pregnant through FET is lesser than getting pregnant through another cycle of IVF , but FET looks like a better bargain as she has less to lose. Somewhere during this journey a woman , may have to chose between 'money left in the pocket' and 'baby in the arms' .

Till 2017 nothing happened .Then I visited a clinic in Banglaore. The doctor threre suggested IUI . The treatment went on for 4-5 months. I am very upset with that doctor. She did not properly diagnose I feel. I also felt she dint give proper support to me. The IUI failed. The doctor said egg is not developing . Doctor suggested IVF. But I dint want to do it there. So I came here . I came to this hospital in 2018. I had a MH of 68 and it was low. Doctors suggested IVF after two months. They suggested Yoga for positive energy and I got 5 eggs. Out of that 3 eggs were good. They transferred 2 eggs and froze the remaining 3. I got a positive response. I was very happy. But then it had to be aborted. The Beta HCG cells were 3000 (very high). Doctors also got shocked . Till two

months I dint know then I started bleeding. I got admitted post abortion . Now they are in the process of FET . They will plant the two eggs which were retrieved last time. The doctors actually suggested to go for another round of IVF cycle, But since I have already spent 6-7 lakhs, I cant spend more. So I thought I ll do a FET and see. If it works well and good , if not let me see. *The eggs fertilized is in a moderate condition. I am not sure how it will work. But I am praying. (*Personal Conversation)

- **Delaying treatment**

Most of the respondents realized about their condition and the root cause of the condition after marraige. However, in some cases there is a possibility to know the condition prior to marriage. For instance in the case of J , she and husband knew that she had PCOD. Ofcourse not all PCOD cases pose a threat to fertility . While some of them said that they sought medical assistance within few years of marriage, some said that they delayed medical assistance even when they knew that they are not getting pregnant . In the case of B and C both (two of the most qualified among respondents) a clear case of late treatment is visible.

- **Travel and Trust in doctors and lab facilities decides their treatment journey**

While most of the respondents found hospitals that can treat them in their own city but there were cases where patients travelled from one place to another for treatments. In case of L she had left her place in Gulbarga and had come to Bangalore for treatment. Similarly, in the case of V she had to leave her place Mandya and travel to Bangalore each time for a treatment. Improper infrastructure in small towns is one of the reasons for people to come to urban cities for treatment. As mentioned by J, people leave their cities , come and find a PG for few days for the treatment in Bangalore. But in all such cases, trust in the doctors experience mattered a lot. Both L and V had heard about the hospital they were getting currently treated and had faith and trust in the hospital. They had done their homework before coming to this hospital.

On their knowledge about treatment

All respondents varied in their knowledge with regard to treatment. While B, Z, L and C could explain the treatment and the procedures, P, A, V , S , J , M, Anjali and H could not articulate and explain the rationale for doing a particular treatment. No respondent gave an impression that they knew exactly what the doctors were doing or what steps they are going to follow in future.

On Alternative medicine

Majority of the respondents were taking Allopathy treatments only except for A and C . Both had taken Unani and Homeopathy treatments respectively before resorting to Allopathy.

On Abiding by doctors advice

Respondents were doing exactly what the doctors advised them to do with regard to treatments. Once the feeling of trust is established between the doctor and patient, the patient abides by the word of the doctor. In two cases however that dint seem to be the case. In the case of P she refused to go for IVF due to cost and in case of B she was not ready to go for Donor eggs as she wanted her own.

On Costs

Almost all respondents said that the initial stage of diagnosis including Consultation, Laproscopy, tests, scans including a IUI had costed them around 50-60,000. For an IUI alone anywhere between 15,000 to 50,000 has been spent. They were not able to give a clear break up of these costs . All respondents quoted IVF treatment cost ranging between 1.5 to 3 lacs. The total cost of treatment where IUI, IVF etc were done together by changing multiple hospitals costed around 6 to 7 lakhs and even 10 lakhs as per one respondent. All of them found the costs to be unaffordable and very high. Most of them felt that it is very expensive. They also felt that cost of treatment depends from hospital to hospital. The fact that it is expensive and on top of that there is no success guaranteed is the greatest woe of the patients.

I have to take almost 15 to 20 scans. Each scan costs 400 Rs. Each FSH injection costs Rs 770 - 1000 Rs. HMG costs 1000 Rs . I travel in autos or in two wheeler. I dont

work . I dont have a count of the money I have spent so far. But all I can tell you is that each time I come to the hospital I have 2000 rs note in my pocket and by the time I reach back home nothing is left. I will have to spend even more

*I stay here in Bangalore. I travel with my mother to hospital. I have so far spent Rs. 65,000 . Each injection costs 3000 Rs to 5000 Rs. I dont work so i dont mind waiting but there are people who work. Waiting time is too much . There are people who come from places as far as Kurnol and the stay in PG's near the hospital to get treated. (*Personal Conversation)

Emotional and Physical

Most of the respondents mentioned that during the course of treatment , they become anxious due to the amount of uncertainity involved in the success of treatments.

The fact that they are spending huge amount of money and it is only worth if treatments are successful is the general mind set. Women undergoing this treatment are not pursuing any career. It seems that the entire time and energy of theirs is spent on the treatment . Although few women had a good career before coming for treatment, they too gradually dropped out. It is emotionally and physically were taxing to work and to go through the treatment.

The harmone injections, scans , treatment and waiting for long hours is a painful exercise. Almost all women mentioned, that waiting long hours is extremely frustrating.

Motivation to carryon with these treatments come from three sources - A great urge to see baby in the arms , family support and encouragement of Doctors .

Of all thirteen women interviewed, none of them felt they are going through a good phase, all felt that they were going through a bad phase. They seemed frustrated, depressed, anxious but at the same time moving ahead with an attitude of this too shall pass on. They were strong. The social stigma of not having a child was bothering them.

Those women who had spent around 3- 5 lakhs or lesser than that , though were concerned about costs but had a feeling that if it works it is worth it. The women who had spent above 5 lakhs around 6-7 lakhs had to make a choice between going into deep debt

or to have a baby. A great disappointment and frustration was visible in the case of P where she shad to either go with an FET or another round of IVF and she decides not to go for IVF and go for FET knowing that the chances are very little.

My career has gone for a toss. I was doing well. But for the last 10 years I am not working. I take some freelance projects . But due to continuous hospital checkups and stress I am not able to take up projects also properly. When treatments dont work it is very disappointing. Each time I come to the hospital I feel very depressed, so I try to get my husband or father along. I come in a metro.I dont like travelling alone. I get my emotional support from my spouse and family

I am tired . Past 5 years I am doing this only. Visiting hospitals getting treated , hope and then despair. It hurts physically as well as emotionally. Me and my husband love kids so we are ready to go through this pain. But i now need a break of 4-5 years. I want to completely forget all this .

*It is a very frustrating feeling. So many injections it hurts , then the process of scanning and then appointments of doctors and dealing with the huge waiting time. Travelling discomfort and time waste is also there. IF you have to come here one whole day gets wasted. I come in the morning , I get appointment by 3 pm. (*Personal Conversation)

On how do they accumulate funds for treatment

Most of the respondents said that the costs are either borne by their Parents or husband. One respondent said that the cost is borne by her parents because husband and inlaws feel that fault is with the girl so her parents only should pay.

My Husband and My mother will pay. (Mother also said- We only have to pay, Inlaws dont know and I dont want them to know. As a mother it is my responsibility to pay)

*My Mother and Father are helping me to fund these treatments. My husband will not give a single penny. They feel that it is the girls mistake and so the girl's parents should pay. (*Personal Conversation)

On anticipation of future costs

All of them knew what portions of treatment was left and what will be the rough costs. Although they were not able to explain clearly in detail. Depending on which treatment and what stage of treatment they are in, the future costs change

On Insurers covering

All of them unanimously felt that insurance companies should cover the costs. When other diseases are covered why not this treatment was the general reaction. Insurers can atleast reimburse 50 % of the costs.

*Wonderful. Are they covering ?(After I told her no).. It will be very nice if they could cover. Even if we get 50% cost of IVF treatment it will be good. (*Personal Conversation)

On what could have helped them.

Respondents felt that right guidance and knowledge of these treatments is very helpful. Wasting time and money in different hospitals and not going for treatment suggested by doctors due to lack of trust is a problem. They also felt that Government should monitor these costs as each hospital charges the way they want.

Some respondents also mentioned that while large corporations such as Wipro covers it's employees and their spouses for such treatment, in small companies there is no provision like that. It should be covered by them too. They also felt that insurance companies should cover these treatments under their health insurance policies.

I just wish I had come earlier here, instead of wasting money somewhere else. When the hospital charges we feel they may cheat us, so we dont say yes immediately. Only when we have trust in the hospital we are ready to spend.

If my husband's side and my husband contributes then it will be good. Right now only parents are spending. I feel very sad to see them spending money. All their money saved for their retirement years is getting spent like this.

My sister-in-law too went for IVF and her husband's company covered it . Companies like BEL ,Wipro their employees get it covered under insurance. But all companies dont Thankfully i have not reached the stage now, what will happen in future i dont know

On which stage insurance will help

Most of the respondents felt that Insurance cover is mostly required for treatment. Respondents who had gone for the treatment only once felt that Diagnosis and Consultation stage can be borne by the patients themselves but treatment can be covered by Insurers. However, respondents who had gone through the treatment multiple times, felt insurance should also cover consultation and diagnosis stage too.

I think till Diagnosis we can bear. Only after the treatment starts and particularly the IVF cost, if they can reimburse even 50 percent it will be good.

The treatment onwards ie scans, injections till delivery it should cover.

*From day 1 insurance should cover till the birth of the baby. (*Personal Conversation)

Part 2

Doctor Interviews

RQ4 How do medical practitioners administer the ART procedures?

RQ5 What will be the effect of an insurance cover on the administration of the treatment?

RQ6 What are the practitioners expectations of coverage from an ART insurance policy?

8.1 Doctors Profiles and Resultsof Interviews

Sr. No	Name	Number of years of experience	Place of Practice
1	D1	10	Works in an infertility clinic (senior consultant)
2	D2	8	Works in an infertility clinic (senior consultant)
3	D3	20	Works in an infertility clinic in a Senior position
4	D4	10	Works in an infertility clinic(senior consultant)
5	D5	10	Works in an infertility clinic (senior consultant)
6	D6	20	Director and Owner of the clinic
7	D7	8	Works in an infertility clinic(senior consultant)
8	D8	20	Senior Doctor , Infertility clinic
9	D9	12	Director and Owner of an Infertility center
10	D10	15	Director and Owner of an Infertility center
11	D11	20	Senior doctor in Hospital providing infertility treatment among others
12	D12	10	Owner of an infertility center
13	D13	10	Director and Senior doctor of a famous chain of infertility center in India

Theme	***Sub Theme***
Definition of infertility	
Number of fresh patients doctors see on a daily basis	
Patients whom they advise go for treatment	
Whether they think if Infertility is growing	
Most important causes of infertility	
Whether Male or female factor is growing more	
ART and treatments included in ART	
Type of demographic profile	
Process followed by doctors	Preliminary workup Baseline investigations Tube Test Counselling and explanation of treatments
Treatments often prescribed	
Why GIFT and ZIFT not done?	
Determines of success rates of treatments	
Affordability of these treatments	
Experience in handling patients	
Injecting multiple embryos	
Phase of treatment cycle insurance cover benefits	
Justification given by insurance company for not covering infertility treatment	

1. **On definition of infertility**

Although all doctors in principle concurred with the WHO definition of infertility ie ' Infertility is when the couple has regular intercourse without the use of any contraceptive for one year and are not able to conceive naturally', some of them had their reservations with regard to the time period of 1 year. As per them the time period of one year should not be cut and dried. It could be more than 1 year or less than 1 year. It depends on circumstances , physical condition of patients, lifestyle, relationship with spouse etc. Their responses leads to believe that time is an important factor which has to be considered before deciding if a patient is indeed infertile. Also three important variables surface while deciding time - Patient's age, Physical condition of the patient , Relationship of the couple (time spent, distance etc),

General definition is Infertility is when the couple has regular intercourse without the use of any contraceptive for one year and are not able to conceive naturally. However, nowadays due to lifestyle, career, distance and time issues, this one year can be increased to 2 years as the number of ovulation cycles may not suffice

*General definition is Infertility is when the couple has regular intercourse without the use of any contraceptive for one year and are not able to conceive naturally .But all those who are above 26-27 , late marriage or with any issues such as PCOD /Endometriosis, Obesity, Tubal factor etc should not wait for 1 year. For them the time is 6 months. (*Personal Conversation)

On number of fresh patients doctors see on a daily basis

Responses

3-4 patients	4
1-2 patients	3
15-18 patients	1
8-10 patients	3

Whether all patients whom they advise go for treatment.

All the respondents said that many drop out. Some said that 50% of them drop out after Consultation and Diagnosis.

Once we tell the treatment cost they try getting the treatment at a cheaper place.

*(*Personal Conversation)

On whether they think in their experience if infertility is growing

All respondents said that , they felt infertility is growing rampantly.

Very much .Alarming to see even very young girls between 23-25 have low ovarian reserve. Also it is increasing in people in IT/ITES

Earlier it was 10 to 15 percent. Now it's become one in six couples every one couple out of six couples are infertile

Very much . Very young couples especially IT/ITES professionals and people with career orientation (10 doctors mentioned on the same lines)

*(*Personal Conversation)

On the most important causes of Infertiltiy

All respondents mentioned Genital Tuberculosis as an important and a prominent caause, followed by lifestyle factors and diseases such as PCOS and endometriosis

Pressure stresses and most people leave the house in the morning and come back in the night, normal relationship, career minded, radiation or they had in the department of radiology

IT/ITES, sedantary lifestyle or people working in hot temperatures or people travelling constantly in two wheeler

Tuberculosis of the genital gland is usually seen in this strata.

In female it's mainly life style changes leading to Polysystic Ovaries.They are career oriented they pospone pregnancy but as they age the ovarian reserves drop I see stress as one main reason in both men and women. In men it is also

Sedentary lifestyle, night shifts, use of digital devices laptops , mobiles etc.

The ones in IT industry who have a sedantary lifestyle or people working in hot temperatures or people travelling constantly in two wheeler

*(*Personal Conversation)

On whether it is male factor which is growing more or female factor

40 percent male	1 doctor
Both are there but male is increasing	1doctor
Female more	1doctor
Both are there and both are growing	8doctors

On what is ART and what all treatments are included in ART

All respondents gave the same answer that ART is Assisted Reproductive Technology Treatments. IUI , IVF, ICSI, GIFT and ZIFT are technologies included under ART

On the type of demographic profile they see.

All respondents felt that they see people from all economic stratas. All respondents also mentioned the fact that though it is unaffordable for lower strata , there is a considerable number of people from this strata who come for treatments.

We see many low socio economic people coming too especially in this hospital. People from higher class also come. Lot of IT people come too.

People from all classes come. We see many women from low socio economic class coming to us. One common cause found in them is Tuberculosis. We also see many young couples working in companies.We see rich people such as head of institutions coming too.

Usually the age group is 23-35 but sometimes above 40- 45 also come.

We have all types of people coming here, right from below poverty line people to head of institutions or organizations. Mostly 25 - 35 years age but sometimes we also get people above 40 max till 45 .

There are many from lower social background, middle class and rich people too come.

*(*Personal Conversation)

On process followed by doctors when the patient come for the first time seeking help

All Doctors spoke in one voice when it came to the procedure followed when a patient comes for the first time. While few explained in detail the procedure, some

explained in short. However, all of them maintained the same order of diagnosis and the same type of tests.

The process can be divided into three parts - A) Preliminary Workup B) Baseline Investigation C) Tube test D) Counselling and explaining the treatment options to patients.

A) Preliminary Workup

1. When a couple comes for treatment , both of them are investigated. Investigation starts with history taking for both of them
2. For a women things such as regularity of period, frequency of intercourse, knowledge of ovulation , knowledge of pregnancy timing, any medical history of thyroid and prolactin or if she is under medication for any hormonal problems or if she has any previous surgical history is checked. If there is any history of endometriosis or if she has had any other abdomen pelvic surgeries it is noted. A physical examination such as BMI and other body investigation is carried out.
3. For a man history checking is done and in case there is any problem found then he is sent to an andrologist.

B) Baseline Investigations

4. For a woman a scan is conducted to look for her uterus and the ovaries. The size of the uterus, presence of any fibroids or any Adenomyosis in the uterus is checked for . With regard to ovaries Antral Follicular Count is checked. Fallopian tubes are checked for any tubal problem such as Hydrosalpinx. It. refers to a fallopian tube that's blocked with a watery fluid.Tubes are normally not seen in a scan but if it is dilated it can be seen in the scan. Later on the second or third day hormone test and blood test is done. Hormone test is to understand the FSH , AMH , ALH ie to check the egg reserve. If a less egg reserve is seen , the couple is asked to go for the treatment immediately. Thyroid and prolactin tests are also done as they have a role in ovulation and the recruitment of the follicle.

5. For a man semen Resultsis done to look for the sperm count , motility, morphology as they play a very important role .

C) Tube test

6. Post the baseline investigation, the fallopian tube test is done. Atleast one tube is necessary for pregnancy. Tube test is not done before the completion of base line investigation as it is a very painful day care procedure and it is done under anesthesia

7. If during the baseline test any problem is identified, efforts are put into the rectify the same . Tube test is recommended only if all baseline investigations show that the woman is normal.

D) Counselling and explanation of treatments

8. Depending on all these tests , Duration of their marriage , age and baseline investigation report counseling is done and different treatment options are explained to them along with their respective costs.

On which treatment among IUI, IVF, ICSI, ZIFT, GIFT is often prescribed ?

Ten doctors felt IUI, IVF and ICSI are the most prescribed , 2 of them said it is ICSI mostly prescribed.

On why GIFT and ZIFT is not done ?

All of them said that , with advent of IVF and ICSI, GIFT and ZIFT has become non relevant. The reason why they dont do it is becausse they have no control of the process which happens inside a woman's body , rather if it happens outside it will be in control.

On what determines the success rates of these treatments

All doctors mentioned that women's age and quantity and quality of eggs, Man's sperm Count and motility, Treatment itself ie ICSI over IVF etc has a better success rate

On the affordability of these treatments and why the costs are different across centers.

All respondents were of the view that generally IVF and ICSI is expensive but IUI is not. There were differing views with regard to reasons for high and differential costs . Lab costs, embryologists fee , Foreign medicines , Consultation were among the most repeated reasons.

Costly lab instruments- such as petri dish Maintenance of lab , embryologists fee , operators charges etc

As mentioned in the words of a doctor who is an owner and director of the hospital ' See I cant do a Laproscopy for 20,000 Rs. While I take the laproscopy equipment on rent for a day, it costs me 10,000, then I have to pay the operator for a day 10,000, the surgeon who comes will charge 10,000, then the hospital bed charges and nursing charges for a day with my consultation fee will be around 15-20,000. If I charge less than that it is not worth the risk I am taking. For 20,000 I might not take the risk at all.

*'We dont use Indian medicines. We have had instances where Indian medicines have harmed my clients. I have almost lost few clients because of the Indian medicines. All these foreign imported medicines are expensive and thus it shoots up the cost of treatment' . (*Personal Conversation)

On their experiences in handling patients who are not able to afford the treatments.

All the respondents felt that many patients took a step back once they heard the cost of the treatment. Cost is one of the most important factors in deciding the treatment. Patients drop out once they hear the cost of treatment. When a cycle fails they lose all

their hard earned money. Sometimes doctors suggest economy packages but at the cost of compromising on the quality of medicines

They(Patients) attend consultations and once the diagnosis is done and we tell them about treatment and its cost, they dont turn up' . Some of them say they will arrange for money and come back. But by the time they come back it is too late, we have to repeat all the procedures again and age ticks away. ' .

' When one IVF cycle fails and we break the news to them asking them to go for another IVF cycle, they are very disappointed, They ask if there is any concession on the second time IVF. Some of them sell everything they have and come for IVF' .

They say ,Can you give us 6 months, do we have to do all these tests, are there any shortcuts,

Sometimes they say doctor we cant afford and then we have certain economy packages which we show, we use Indian drugs instead of imported ones.

*(*Personal Conversation)

On whether multiple embryos are injected so as to avoid extra costs of another cycle.

Unanimously all doctors said they go by strict guidelines and they dont insert more than 2 embryos. Some gave justifications for inserting 2 embryos instead of 1 and 1 embryo instead of two . Reason for inserting 2 embryos instead of 1 is to improve the success rate and 1 instead of 2 is in cases of sub fertile patients where they already have a child.

We dont inject more than 2 embryos . The reason for injection 2 (more than 1) embryo is that the success rate is better

We inject usually 2 embryos .Sometimes we insert single embryo also when parents say they already have a child and they dont want twins.

If body condition is bad all embryos irrespective of you put 3 or 4 will die. So we dont put more than 2, we freeze the rest of them and we do transfer of embryos at a later stage.

*(*Personal Conversation)

On which phase of the treatment cycle insurance cover will benefit the patients the most (Consultation , Diagnosis, Treatment, Surgery, Inpatient, Administration of Drugs pre-post treatment)

All doctors felt that the treatment stage is the most expensive and it should be covered. However, with regard to coverage of other stages , views were varied. It has been presented below –

From Treatment and Surgery stage till Administration of drugs post treatment. Consultation and Diagnosis stage is not required	2 Doctors
All stages it are required.	6 Doctors
From Diagnostic stage till post treatment drugs	2 Doctors
Need not cover Consultation and all diagnostics except expensive ones such as laproscopy. Thereafter treatment till post treatment drugs	2 Doctors
Pre post treatment, inpatient is not required. All treatments, surgeries, injections and lab tests are expensive it should be covered	1 Doctor

Views on justification given by insurance companies for not covering infertility treatment (That infertility is not a disease)

All Doctors felt infertility is a disease and Insurance companies should cover the same. It is indeed physiological mal function. It can be a resultant of a disease such as T.B , PCOS or endometriosis, but finally the end result is also another disease .

Lets take a case of women whose both the tubes are blocked due to tuberculosis , that is an infection which lead to the defect in the body. Similarly , a lady of 25 years with very less ovarian rerserve, eg. AMH of 0.25 where it should be 3 or 4 , she is not normal. She is going through some physical problem. How can we say it should not be covered. Are they not going through pain. There is an emotional pain attached to it as well. A social stigma attached too.

*Infertility is no longer a defect it is soon becoming a disease. It will lead to poor mental health such as depression Defect is going to lead to a disease so we need to treat it at a defect stage so that it does not become a disease. They must cover all infertility treatments . (*Personal Conversation)

Part 3

Insurance Experts Interviews

Research Question - How to put the drafted framework in to practice ?

9.1 Introduction to the Respondents (Names have been masked) All the respondents had experience with health insurance.

Sr. No	Name	No of years of experience (approx)	Work Profile
1	I1	15 years	Head , Business Development , South zone of a reputed Private insurance company
2	I2	30 years	Retired from a reputed Public sector company with 30 years service, currently working with a Broker
3	I3	20 years	Administrative officer, with a reputed Public sector Company
4	I4	15 years	Administrative officer, with a reputed Public sector Company
5	I5	15 years	Administrative officer, with a reputed Public sector Company
6	I6	15 years	Independent Insurance Consultant
7	I7	10 years	Fellow , Insurance Institute of India, Independent Consultant
8	I8	30 years	Retired General Manager from a Public Sector Company and works currently with a quasi judicial body
9	I9	20	Works in a senior position with a T,P.A
10	I10	20	General Manager, Reputed Private insurance company

Themes

Inputs on development and design of a new health insurance product

Reasons for not coming up with ART products
Coming up with exclusive product
Buyer of the product
Opinions about coverage, add on covers, exclusions and conditions
Risk sharing options with customers

Age of entry
Term of the policy
Arriving at sum insured
Benefits/Packages
Settlement claim process
Administrating implications
Role of hospitals
Marketing aspects
Risk in rolling out ART product
Support from government and IRDA
Business Model

Inputs on development and design of a new health insurance product

A new insurance policy is designed based on the insurance needs of the insuring public. A market study is conducted to ascertain the insurance requirements of the public at large and would explore to devise a policy to take care of the said insurance needs.

After opening up of the industry in 2007, the insurer's approach has undergone a sea change in product designing and meeting with the requirements of the customers. Mostly private companies have started operating with an alliance with any of the foreign company. They have started introducing the products available
elsewhere in the world to India. Moreover the requirements of the customers in India have also started changing and the products offered by these companies in tandem with the changes happening with the buyers. Significantly it could be a shift from sellers market to buyers market.

On why Indian Insurance companies have so far not come up with ART products

1. Most of the Insurers do not regard infertility as a disease and hence no cover is designed (6 out of 10 respondents)
2. Insurers find it operationally difficult to operate due to presence of Moral hazards and unregulated Infertility clinics.

3. They also feel Health is a bleeding portfolio , to give such a cover will mean more losses.

Basically Health policies provide coverage for diseases/illnesses. Reproduction is a natural process and not a disease.

The market for ART is relatively small and hospitals/clinics providing health care are unregulated.

Health insurance is a loss making portfolio. The premium received barely covers the claim. This is very difficult to cover .

When can we give the client more, only when we are satisfied and we are in a position to give. Right now the situation is so bad. There are several covers which we think can be covered , we feel they are genuine needs but then we are not able to becuase of the fact that we are already in a loss. On top of that moral hazards are huge in health

We dont regard pregnancy as an ailment. Only under Group policy we give maternity cover as an add on . Under happy family floater policy under a plan named as Diamond plan we give claim but that too only 25% of the claim is allowed. And any such ART treatment is outrightly considered as an exclusion and we dont consider it at all. Even in Add on our company does not give ART at all.

Child birth is not a disease. It is a gift to the parents . As such maternity is an exclusion, only for certain policies such as group with additional premium we consider. So even if someone has bought the maternity cover as add on we give only 50,000 and another complication such as miscarriage etc we don't give. So where is the question of covering ART (Personal Conversation)

On coming up with an exclusive product on Assisted reproductive treatment policy

1. It is a bad idea to come up with an exclusive ART product (9/10 of them felt said so) Only one respondent said , it will be required in the near future.

2. Most of them agreed for an add on cover (8/10 ; 2 respondents felt there was no need even as an add on. Surprisingly, the 2 who did not agree, their company's policy, already has ART as an add on in family floater and group insurance policy.)
3. A product can be designed restricted only to the lower strata of the society
4. Reasons quoted for 'Why an exclusive product wont work' are as follows.
    - Difficult to convince that he/she will become infertile in the near future and hence should buy a policy
    - Fear of moral hazards from hospitals side and that it will become a business.
    - Such a cover will increase the cases of voluntary fertility
    - Already population is an issue, this is not required
    - Focus on meeting the needs of the ones alive

I have got queries even from unmarried people for maternity coverage. We have 4 years as waiting period for a maternity cover. So people are ready to buy health policies with maternity cover in anticipation of the fact that they will require it in near future. But they will not be ready to accept the fact that they will become infertile in the future. Unless there are people where PCOS runs in their family. To convince them for infertility cover only as a standalone is extremely difficult . I doubt it will work out.

Exclusive product for ART is a bad idea. Add on is better. Not all people will require this treatment. Already in country like India population is a blessing why would people buy this policy

As a lady I wish there were policies of such sort , but as an Insurer its a 'No' I am afraid this cover will increase the cases of infertility treatments. I believe most of them are voluntary infertility cases. Technically, the policy if designed should cover only those who have tried everything and are not able to conceive naturally and the genuine cases.

As an insurer, I will not encourage this policy as I feel hospitals will take advantage of this. Even if patients can give birth naturally by waiting for couple of years , hospitals will encourage for ART I feel. Ceasaran is an example. Even if mother can give birth naturally, many doctors advise C-Section. In India we treat Doctor as God. So whatever they say we do. People will not even go for a second opinion. In our opinion, the hospitals have become completely commercialized. They have spent lot of money to become doctors and have invested in hospitals so they have to take it back. We settle Mediclaim claims and this is what we see most of the times. Doctors suggest irrelevant tests . If we start this product, we know for sure, out of 100 percent deliveries 50 -60 percent will become IVF deliveries only, whether it is genuinely required or not. Also

people have become career oriented , with this policy they will postpone conception even more.

In my opinion the cover should be restricted to lower middle class and poor people who have infections and diseases because of which they are not able to conceive. A woman who is not able to conceive especially from a lower strata goes through lot social problems.

I am not in favour of any of them. This should remain as an exclusion. You have so much of population issues there is no need for this cover now. Lets try to solve problems of those who are alive and who need treatments.

Many people suffer from infertility and ART is in big demand. With the increase in the market for ART, insurers may now look at introducing a suitable product.

*(*Personal Conversation)

On who can be the buyer of the product?

1. Married Couples- Prospective couples -(8 responses)
2. People who buy family floater (2 reponses)
3. Women of reproductive age (2 reponses)

On opinions about coverage, add on covers, exclusions and conditions of this product ?

There were diverse opinions with regard to this question. Each respondent spoke with his own experience of handling health insurance domain.

The cost of the treatment including diagnostic tests, treatment being given either on OPD basis or as an in-patient needs to be covered.

Claim should be admissible only if treatment is taken a hospital/clinic approved by the Government of India for this purpose.

The policyholder should inform the Insurance Company before proceeding with the treatment with the relevant medical records.

There should be a waiting period of minimum 4/5 years and the policyholder should be entitled for treatment after completion of the waiting period only.

No claim should be admissible for the treatments commenced or taken up prior to completion of the waiting period.

The policy should be valid as on the date of confirming the failure of the treatment.

The Insurer should fix the number of cycles.

Surrogacy can be excluded as in India Commercial surrogacy is excluded.

*(*Personal Conversation)

On some risk sharing options with customers to make this product successful

All 10 respondents mentioned that Insurers should incorporate a high Co-opay and sub limit for ART policies (as high as 50%) .

Rationale for high co-pay is to make the insured responsible about the costs of treatments (which other wise they would take it hands down when the doctor prescribes a treatment)

Sublimit of not exceeding 50% of the cost of treatment and a Co Pay of 50% will be good

Copay can help provided it is well understood by the clients.

Generally, we put a slab anything above is paid by the client himself. That is to ensure that any additional extra treatments by doctors are not covered insurers and insured himself takes responsibility of the extra costs.

(Personal Conversation)

On the minimum and maximum age of entry for this product

All respondents believed that the reproductive age(Minimum 18 and Maximum 40) is where the insured needs a protection for

The entry age and maximum age is reproductive age ranging from 18 years to 40 years.

The underwriter may fix a preferable age group from 18 years to 30/35 years where the reproductive opportunities are more.

*(*Personal Conversation)

On the term of such a policy

All 10 respondents said that health policies are annual contracts. So it should be for 1 year. 1 Respondent felt it can be for 2 years also.

On how to arrive at a sum insured for this type of policy

Those respondents who belived that the an add on would better work and there is no need for another stand alone product, did not answer for the question. There was no point insisting them to answer as they did want a seperate calculation.The responses of the others were on the below lines -

Sum insured should be based on geographical location and categorization of the hospitals and treatments.

The standard of living and requirements of insured in terms of treatments can be as base for deciding sum insured.

(Personal Conversation)

On dividing the various benefits into various packages.

Majority of the respondents felt that mediclaim model is best to be followed to divide the benefits.

Few also felt that room rent can be a base for settling the claims.

Ideally Room rent is the base for settling the claims. All tests, consultation, treatment, xray , even surgeries are based on room rent

. *(*Personal Conversation)

On the process required for settlement of claims

Most of them felt that , since the chances of moral hazards is high, insurer should be very careful in settling the claims.

Prior intimation and approval from insured before starting of treatment

Whether a claim is genuine or not depends on the fact whether the test was indeed required or not; thus the insurer needs to check if there was any treatment done after investigations .

Prior intimation should be made to the Insurer before the commencement of the treatment which would give an opportunity to the Insurer to verify the credentials of the treatment during its course itself.

The most crucial thing is to understand if the investigation was followed by any treatment. We see that patient would have gone for a headache and doctor suggests an MRI . Like this CT scan too.. All these scans are around 7000 Rs. Yes if Scan shows that there was a problem and then treatment has been given after that for making him recuperate , we can consider. Otherwise , they (hospitals) will simply take scans , after all they have invested in a machine, from where they will take the money out. I am worried the same can happen for IVF also.

(Personal Conversation)

For the insurer, from the administrative stand point what would be the implications of rolling out such a product.

Most of the respondents felt , that this being a health product , has similar administrative functions, except for the fact that, the presence of moral hazards and a new domain makes it more compliance oriented.
Also, balancing between the claim settlement and premium would be a challenge.

Heavy reliance on Third Party administrators, makes compliance more essential.

Unhealthy practices of the hospitals requiring more stringent compliance to be followed.

Employing experts from medical line to check genuitiy of claims. Heavy reliance on TPA

The only challenge is how will they balance the claims and premium is a big challenge. *(*Personal Conversation)

On the role of hospitals in client servicing?

There were mixed responses for this question . Four of the respondents felt that hospitals should not be given any role as they may not have enough time . One respondent also felt if these products are routed through hospitals, there will be instances of moral hazard. However, the others felt that hospitals can be a great source of disseminiation of information.

The problem is that the hospital may tend to go out of the way to help the patient to get the claim of their patient, if the product is sold by them.

I dont think hospitals should be given any role. Hospitals are crowded and they wont have enough time.

*(*Personal Conversation)

On the marketing aspects (Target market, Pricing, Promotion, operations and distribution, Point of sale)

Most of the respondents felt that the traditional way of operating through T.P.A, hospitals and agents will work. Unanimously all suggested the target market to be from the reproductive age group. While few suggested traditional views on promotion few also felt that promotion will have an adverse affect and threats of moral hazards would creep. For point of sale, the underwriters office was the best choice. All of the respondents felt that sales men will face troubles while selling the product as people may not easily buy such a value proposition.

- Distribution

Traditional way of distributing through T.P.A's, hospitals and Agents is good.

- Target market

Reproductive age group -18-30 , 30-35 not recommended. The chances for the females to conceive becomes relatively quite less after attaining age of 30

- Pricing

Based on the geographical categorization and grading of hospitals which ultimately depend on the cost for the each procedure.

- Promotion

No promotion is needed

Creating an awareness of the product through the print media, televisions and through internet. FMs may also be used.

It should not be promoted. Whoever wants it will take it. Promotion will attract moral hazards.

- Point of Sale

*The point of sale would be the Underwriter's office only. *

Lack of awareness of the product and usage of unscrupulous means in issuing the policies makes it important that the policies should be sold from underwriters office only

*(*Personal Conversation)

On risks foreseen in rolling out an Assisted reproductive treatment product and how can it be mitigated

- All ten respondents mentioned moral hazards due to unhealthy practices of hospitals .
- Few also mentioned less success rates (as repeat claims may arise in case of failure)
- One respondent also mentioned misrepresentation of material information from patient's side. However, all of them felt the risk for moral hazard is more from hospitals side compared to insured, due to lack of knowledge about the subject.
- Managing and mitigating of risks can be done thorough copay, empannelment of hospitals, fixing a sum insured and setting sub limits, bringing in a more rigorous framework by taking help of government agencies where legally someone can be made accountable

One way to implement this cover is to have a higher premium . With that the moral hazard from doctors side will be reduced as the customer himself will be more alert. He will not go for the treatment unless he feels it is very much required. I think Co pay option will work. It will make him responsible and do all the homework, behave as if he is uninsured do all the trial and errors and when they are very sure there is no other

go only then go ahead with treatment and we also as insurance companies we will support them

*Atleast for the weaker sections if insurance is provided under workmen's compensation, due to rigourous legal framework, the hazards will automatically get reduced. (*Personal Conversation)

On support from Government and IRDA

Most of the respondents felt that for the weaker sections , Governmnent can provide a subsidy so that such this kind of treatments can be afforded by them through a policy . Government intervention for reduction of moral hazard from hospital side , taking help of CSR and IRDA's help in bringing this project out on a Piliot basis were the other responses.

Government should provide a kind of subsidy to economically weaker sections for taking this kind of treatment so that such segment may also look for this policy.

Government may bring out a kind of stringent action against the hospitals using unapproved methods of ART. This will promote the ART through legitimate hospitals.

IRDAI may also provide approvals for this kind of policies on pilot project and provide encouragement to the insurers promoting this product.

This can be brought under the CSR ambit. Hospitals can help the weaker section of society by providing consultation and few treatments free of charge.

Similarly Insurance company and Government can help too.

*(*Personal Conversation)

Apart from the traditional business models for health insurance products, what type of business model would suit such a product

All ten respondents felt , that Insurance domain is more on the service side than on the business side. The principles of health insurance was quoted by few of them such

as sharing the risk, equity, affordability. Though all felt that it is indeed a tough value proposition, there is a way to work forward by bringing in many stakeholders together and doing the right math for premium . Taking help from Reinsurance companies also has been suggested.

> *This is more on service side. You should think of getting all stakeholders together and helping the needy but ensuring no one is at a loss. For the upper middle class people, if this product is sold, it should have higher premium and higher copay.*
>
> *Another aspect is that insurance companies can adopt a reinsurance business model for such health policies . So that the risk is spread.*
>
> *(*Personal Conversation)

Discussion

The results of the study have been discussed in this chapter under four super ordinate themes namely Availability, Treatment, Affordability, Insurance Coverage.

Super ordinate Theme	**Sub Theme**
Availability	*Role of Education in getting treated* *Lack of Trust in hospitals - Low Success rates- High Costs and Fear of losing both Money and child* *Patients level of knowledge wrt treatments*
Treatment	*Causes of infertility in women in India* *The treatment journey* *Wrong Diagnosis - Unnecessary IUI, waste of money and delay in the right treatment* *Battling with Anxiety and Depression* *Starting the infertility treatment* *Process followed by doctors* *Consistency in procedures*

Super ordinate Theme	*Sub Theme*
Affordability	*Cost decides the treatment* *The feeling of No Money - No Child* *Financial worries come in between the treatment of patient* *Juggling to make the treatments affordable for the patients.* *Treating the poor*
Insurance Coverage.	*Framing of Insurance Policies* *Components of an Assisted Reproductive Technology Treatment Insurance Framework* *Ppractitioners'' expectations of coverage from an ART insurance policy?* *Bursting the myth - Infertility treatments are not covered in India by Insurance companies* *The rich gets the cover - The poor does not* *The status quo* *The reason for resistance in covering infertility treatments* *The way out - Solutions on designing a robust framework (Insurers perspective)*

Treatment

Causes of infertility in women in India

The causes for infertility in women in India can be divided into three categories.

1. Infections, 2. Life style diseases 3. Environmental and Health Hazards

1	Genital Tuberculosis
2	Polycystic Ovarian Syndrome
3	Celiac Disease
4	Chalmydia trachomatis
5	Obesity
6	Variations in Androgenreceptor
7	Heavy metal and pesticide exposure
8	Endocrine disruptors
9	Cancer treatment drugs such as Methotrexate
10	Lead, Certain ethylene glycol, Carbon disulfide (CS2),
11	M Genitalium
12	Ionising radiation, X-rays and gamma rays,
13	High biomass smoke levels, high emission factors, exposure to dust
14	Nutritional deficiencies

Her journey depends on the first doctor she consults and what age she consults

In a Woman's life the phase of going through an ART treatment is undoubtedly one of the most anxious, uncertain, painful, desperate, vulnerable, sad ,disappointing and hopeful times. Women feel alienated and frustrated . ***Kaliarnta etal (2011)*** The struggles she faces emotionally, financially and physically is something only the one who is going

through can describe. The whole journey she undertakes is usually more than 3-4 years and sometimes 5-6 years too. In the initial days , the knowledge she carries about her bodily condition and the reason why she is unfertile is minimal. For the first few years, she goes through a phase where she is unsure of what she wants. How long each woman waits before consulting a doctor is completely dependent on her age and any knowledge about her previous body condition which may indicate infertility and , interest in bearing a child and support of spouse. *Those women who said that their spouse was also keen on having a child had visited the doctor at a very young age. Women who belong to a upper middle class/ rich strata directly go to a big and famous hospital to consult gynecologists. The middle class and below strata , go to a gynecologist in their locality. But one thing common in both is that none of them go directly to infertility clinics. This shows that the first point of contact is the local gynecologist or family gynecologist*. Depending on the gynecologist's experience and knowledge the fate of their journey's change.

Wrong Diagnosis - Unnecessary IUI, waste of money and delay in the right treatment

Detecting where the problem lies , whether it lies in the male or female and which particular physiological malfunction is resulting into infertility is the most crucial point. *Few doctors and clinics do this job meticulously, step by step and religiously. But some doctors dont. For eg. Laproscopy of the tubes is a step to be done to check if fallopian tubes are fine, but some clinics without going for laproscopy prescribe an IUI* . The reason is laproscopy is painful and it costs 50,000 Rs. whereas an IUI costs around 15,000 and is not painful. In a way this may not be wrong. If a woman conceives after IUI is done (assuming there was a case of male factor infertility), she is saved of a painful and costly procedure. To give an analogy, suppose a person is returning from the airport to his home and enroute he stopped to buy a gift and finally when he reaches home and he realises that he has kept lost a bag . He has a hunch that he has mostly forgotten it in the airport but he cant rule out the gift shop too. He goes first to the gift shop to find as it is nearer to him just to rule out this option (though he is mostly sure that he has forgotten it in the airport). The human mentality is to first rule out an easy option and then go for the tough option. In the similar manner, the doctors rule out the IUI option first when

they are not sure what exactly is causing infertility. We must also remember that there are many clinics who are level 1/level2 who have been authorized to do an IUI. Assuming a patient visits such clinics , the doctors may make some money by IUI. But level 1 and level 2 clinics mostly dont have laparoscopy facilities. With IUI patient is happy that there is one infertility test done , thus every patient visiting a small clinic ends up getting an IUI done, be it a case of female infertility or male infertility .Sadly there is research which also says that identifying and correcting possible underlying pathologies by laparoscopy may subsequently enable natural conception and avoiding infertility overuse ***Pantou (2019)***

Battling with Anxiety and Depression

Patients go through a phase of frustration and depression ***Kaliarnta (2011).*** On one side they are not able to pursue any work/career on top of that the high waiting time in hospitals followed by painful injections make them feel depressed. *In the words of B - My career has gone for a toss. I was doing well. But for the last 10 years I am not working. I take some freelance projects . But due to continuous hospital checkups and stress I am not able to take up projects also properly. When treatments dont work it is very disappointing. Each time I come to the hospital I feel very depressed, so I try to get my husband or father along.*

When can we call a patient Infertile and put her on a treatment ?

Infertility is definitely a disease as it is a result of a physiological malfunction. All doctors strongly believed that it is a disease which needs treatment and it must be insured. Infact many felt , it affects a human being emotionally too and a patient consequently may succumb to mental illness In the words of Dr. D5 and Dr. D2 respectively *'Lets take a case of women whose both the tubes are blocked due to tuberculosis , that is an infection which lead to the defect in the body. Similarly , a lady of 25 years with very less ovarian rerserve, eg. AMH of 0.25 where it should be 3 or 4 , she is not normal. She is going through some physical problem. How can we say it should not be covered. Are they not going through pain. There is an emotional pain attached to it as well. A social stigma attached too.'*

Infertility is no longer a defect it is soon becoming a disease. It will lead to poor mental health such as depression Defect is going to lead to a disease so we need to treat it at a defect stage so that it does not become a disease. They must cover all infertility treatments .

In the first stage the administration of the treatment only starts after understanding the infertility status of the patient. The definition of the word infertility is quite different from the definition given by WHO . In the words of Dr. D10 *General definition is Infertility is when the couple has regular intercourse without the use of any contraceptive for one year and are not able to conceive naturally. However, nowadays due to lifestyle, career, distance and time issues, this one year can be increased to 2 years as the number of ovulation cycles may not suffice*

General definition is Infertility is when the couple has regular intercourse without the use of any contraceptive for one year and are not able to conceive naturally .But all those who are above 26-27 , late marriage or with any issues such as PCOD /Endometriosis, Obesity, Tubal factor etc should not wait for 1 year. For them the time is 6 months.

Thus the decision of whether the treatment can be started or not depends solely on the understanding of the doctor about the age, physical condition of the male and female, their prior medical records, and current relationship status ,lifestyle, work/career etc. Thus each doctor has a different time line before he or she decides how long can the couple wait after marriage to be called as infertile and start the treatment. Each doctor uses their own judgement. There were many cases such as Z and J were just 24 and yet they were on infertility treatments . Both Z and J suffered from PCOD. All the doctors when asked what procedure they follow when a patient comes for treatment said more or less on the same lines.

Process followed by doctors when the patient come for the first time seeking help

All Doctors spoke in one voice when it came to the procedure followed when a patient comes for the first time. While few explained in detail the procedure, some

explained in short. However, all of them maintained the same order of diagnosis and the same type of tests. The process can be divided into three parts - A) Preliminary Workup B) Baseline Investigation C) Tube test D) Counselling and explaining the treatment options to patients.

A) Preliminary Workup

1. When a couple comes for treatment , both of them are investigated. Investigation starts with history taking for both of them
2. For a women things such as regularity of period, frequency of intercourse, knowledge of ovulation , knowledge of pregnancy timing, any medical history of thyroid and prolactin or if she is under medication for any harmonal problems or if she has any previous surgical history is checked. If there is any history of endometriosis or if she has had any other abdomen pelvic surgeries it is noted. A physical examination such as BMI and other body investigation is carried out.
3. For a man history checking is done and in case there is any problem found then he is sent to an andrologist.

B) Baseline Investigations

4. For a woman a scan is conducted to look for her uterus and the ovaries. The size of the uterus, presence of any fibroids or any Adenomyosis in the uterus is checked for . With regard to ovaries Antral Follecular Count is checked. Fallopian tubes are checked for any tubal problem such as Hydrosalpinx. It. refers to a fallopian tube that's blocked with a watery fluid.Tubes are normally not seen in a scan but if it is dilated it can be seen in the scan. Later on the second or third day hormone test and blood test is done. Harmone test is to understand the FSH , AMH , ALH ie to check the egg reserve. If a less egg reserve is seen , the couple is asked to go for the treatment immediately. Thyroid and prolactin tests are also done as they have a role in ovulation and the recruitment of the follicle.

5 For a man semen analysis is done to look for the sperm count , motility, morphology as they play a very important role .

C) Tube test

6. Post the baseline investigation, the fallopian tube test is done. Atleast one tube is necessary for pregnancy. Tube test is not done before the completion of base line investigation as it is a very painful day care procedure and it is done under anesthesia

7. If during the baseline test any problem is identified, efforts are put into the rectify the same . Tube test is recommended only if all baseline investigations show that the woman is normal.

D) Counseling and explanation of treatments

8. Depending on all these tests , Duration of their marriage , age and baseline investigation report counseling is done and different treatment options are explained to them along with their respective costs.

Do all Doctors practice in the same manner as prescribed above ?

All may not be practicing exactly on the same line as they said. ***For instance, while interviewing Dr. D12 she mentioned all the above listed steps . But when her former Patient P was interviewed she said that the doctor had performed IUI on her which failed.*** Later another hospital suggested IVF since eggs were not developing. Dr.D12 had done IUI on P without properly diagnosing the real reason for infertility. In Ps' words *Doctor suggested IUI . The treatment went on for 4-5 months. . I am very upset with that doctor. She did not properly diagnose i feel. I also felt she dint give proper support to me.*

Does that mean the hospitals where they follow the procedure properly will have better success rates. Not necessarily. In the same case , when P finally came to one of the finest hospitals in Bangalore, she was put on IVF. Initially the results came positive and then later it failed shocking the doctors.

In her own words ' I came to this hospital in 2018. I had a MH of 68 and it was low. Doctors suggested IVF after two months. They suggested Yoga for positive energy. and I got 5 eggs. Out of that 3 eggs were good. They transferred 2 eggs and froze the remaining 3. I got a positive response. I was very happy. But then it had to be aborted. The Beta HCG cells were 3000 (very high). Doctors also got shocked

The technology is at a nascent stage. The doctors using it are still learning . Each unsuccessful case is a learning for the doctors.

Availability

The availability and accessibility of these treatments is poor. The factors such as Education, Lack of trust in Hospitals and high hospital charges, and lack of knowledge among people seeking treatments make these treatments less available to common public. The factors have been discussed in detail below-

Education does play a role in getting treated

Both in the case of L , where she had PCOD and Thyroid and the Gynecologist referred an IUI and later they started IVF in another hospital and *in the case of Vijayalkshmi* where though a doctor detected Intestinal Tuberculosis the Gynecologist performed an unsuccessful IUI and later on she had come to another hospital for IVF. L is a well educated urban woman from a upper middle class background and V though is educated she is from a small town and from a lower middle class background. Does education and strata have any role in a doctor prescribing IUI ? There is research to show that educational attainment and outcomes of infertility are related ***Mahalingiah (2011)***

Lack of Trust in hospitals - Low Success rates- High Costs and Fear of losing both Money and child makes women delay the treatment

Even if patients land in the hands of good doctors who are able to diagnose the problem and suggest the right treatment for eg an IVF , patients are unwilling to accept the fact that they have to go for an IVF right away. The cost drives them away. *For instance in the case of B* she was told by a reputed hospital to start IVF with donor eggs

but she did not. Instead , she took a break of few years and later when she came to this particular hospital and when they too suggested the same thing, she is now contemplating whether to take it up or not. ***Almost all patients had visited atleast two hospitals before they decided to go for treatment in the third hospital***. There are two reasons for this behavior. The first one being trust in the doctor. However, reputed the hospital is or doctor is, it is difficult for a patient to completely trust the doctor for a treatment which requires immense courage to go through a path which is unsure, unventured and above all very expensive. Patients are used to a doctor saying, 'This treatment will make you alright' but doctors saying 'This treatment may make you alright' is not what any one wants to hear. With less chances of success and spending all the hard earned money and coming back to square one is exactly what most of the patients dread and thus they delay treatments. But the same situation when it is patient's own life or a near and dear one's life, they dont think twice. Thus , patients feel , saving their own life is a necessity but to have a child is not a necessity. India has been predominantly a poor country and whether rich or poor , all know the value of hard earned money , unless they have huge wealth. Putting money somewhere without knowing whether it will be successful or not is still viewed as luxurious proposition for atleast the upper middle class and the classes below that . Hospitals have understood this very well. Thus the right marketing strategy is to show higher success rates. All IVF patients had agreed to the treatment because of the success rates and trust in the hospital. Some of them travel different cities and stay for a while to get treatments done due to the reputation of the hospital.

Patients level of knowledge about the treatments they undergo is varied

For instance L, V, Z , B, C ,J could explain what exactly was happening, whereas H, G , M, S , P and A had less knowledge.

Affordability

One of the reasons these treatments are out of reach of common public is because of poor affordability. On one side , the patients are unable to afford and another side, doctors are unable to describe good treatments and medicines considering the fact that they are not able to

Cost decides the treatment

While some patients are lucky to get success through IVF in the first instance, others are not. After spending 6-7 lakhs when an IVF fails they come to a stage where they have to decide whether they can accumulate more money to give it another shot. ***In case of P as she mentions*** ' *The doctors actually suggested to go for another round of IVF cycle, But since I have already spent 6-7 lakhs, I cant spend more. So I thought I ll do a FET and see. If it works* well and good , if not let me see. *The eggs fertilized is in a moderate condition. I am not sure how it will work. But I am praying'* Though she knows that FET has less chances compared to IVF she wants to take these less chances compared to better chances just because she cannot afford it.

No Money - No Child

M had to completely get dropped of the treatment because she could not afford it. In her own words ' *We have no money so we have no child, if we had money we would have a child'*

Who pays the price for infertility treatment ? Spouse ? In laws ? No its The mother or father of the infertile woman who ends up paying

When it comes to taking the responsibility of funding the treatment it looks like when a women realizes that the infertility is due to her physiological condition, she and her family (parents) decide to take up the responsibility. Although , in few cases the spouse was supporting , no where the spouse's family had financially supported. Essentially it looks like it's either the woman's problem or her parents problem. In few cases even spouses dont support . In words of A ' *My Mother and Father are helping me to fund these treatments. My husband will not give a single penny. They feel that it is the girls mistake and so the girl's parents should pay'*

Financial worries come in between the treatment of patient- Thus making the doctor anxious

As all doctors mentioned more than 50% of the cases dropout once they get to the know the cost fo the treatment from the doctor. They surpass the consultation stage, doagnostic stage, and finally when the doctor suggest IVF they listren and go and then they never turn back or they ask for some short cuts in processes to afford the high costs. In the words of Dr. D3 ' *Whenever we counsel them, upfront what could be the various charges they would tells that we cant afford it, give us 6 months or is it some other way, , do we have to do all these tests, are there any shortcuts ? 'We dont use Indian medicines. We have had instances where Indian medicines have harmed my clients. I have almost lost few clients because of the Indian medicines. All these foreign imported medicines are expensive and thus it shoots up the cost of treatment'* Doctors said patients sometimes sell their everything

Juggling to make the treatments affordable for the patients.

Ironically as per Dr. D8 ***when a patient says she cannot afford a particular treatment package, we offer her an economy package***. Unlike the regular package the economy package consists of Indian medicines. Dr. D8 is an extremely senior doctor with a very famous hospital and Dr. D3 too is a very senior doctor working for another very famous hospital. This means that the hospital is compromising on the health of the patient by prescribing Indian make medicines.

While the patients hop and jump from one center to another center hoping to get a treatment at a lower cost, they end up spending more money on repeating the diagnostics at every hospital again. In the words of Dr. D10. Once we do laproscopy and find the problem and I know that through IVF they can conceive and when I tell them it will take 1 to 1.5 lakhs they say they will come back after arranging for money. They take a break of 6 months to an year and again they go to another hospital where they do same set of scans and laproscopy again. I feel very sad for them.

Treating the poor will be easy

One of the major causes of infertility quoted by doctors is Tuberculosis which affects the reproductive organs. This is found from women in lower strata of the society. Since Genital tuberculosis does not show any symptoms in early stage only when a women comes after many years complaining of a problem of not being able to conceive , only then it gets detected through laparoscopy. Laparoscopy itself costs close to 50,000 and since women may not be able to afford , dont get it done. Its a myth that only the rich who can afford such treatments come to infertility clinics, many who come, come from lower middle class. In the words of Dr. D3 - *I personally feels that if we look at the lower social economic group they come across asking for investigation and treatments much later than compared to someone who is of a higher economic background. And the simple reason for this, is that group of patients have some kind of disease say*

Tuberculosis. Their awareness is low and due to the money factor they come to the hospital much later. Because the patients are not able to afford another cycle of IVF doctors advise FET knowing that the chances of success are less. But since the patient does not have enough money to go for IVF they do FET thus treatment is done keeping in mind the affordability of the customer.

Insurance Coverage

In order to create policies a sound framework is required and since in India a framework to create ART policies is not available, there was a need to look outside India. While interviewing the insurers , their real concerns with regard to non coverage of ART and the presence of probable moral hazards being a detriment to create such policies surfaced.

Framing of Insurance Policies

The study of public funding frameworks clearly explains that each country's philosophy is different and is driven by Government spending capacity and also the current infertility rates of the country. For instance , a country like Japan which has been facing low fertility rates for the past few years has an extremely supportive public funding system. Denmark, Belgium , Canada, New zealand have full public funding . But there is a great variance in the number of cycles allowed. While Canada has conservative approach of 1 cycle, Countries such as Belgium allow 6 , New zealand allows 2 and , Denmark allows 3 cycles. All countries allow till 40. Some countries such as Sweden even allows till 45. With regard to Marital status some countries such as Belgium, Newzealand Finland allow for Single and Same Gender too. But few countries such as Germany, Singapore, Honkong allow only for married couples. Ireland and Austria ask for a stable relationship between heterosexual couples but marriage is not required. Number of embryos allowed vary. For instance, Sweden allows max 2 embryos, Japan and Honkong 3-4 embryos, Australia allows less than 1 for less than 35years of age and 2 for more than 38 years of age, Norway allows only single embryo transfer. The rationale could be on the dwindling fertility rates of the country.

An Assisted Reproductive Treatment Framework has to be developed on the basis of the following factors. These factors decide the coverage, the cost of insurance and the risks undertaken by the Insurer.

Components of an Assisted Reproductive Technology Treatment Insurance Framework -

Section A - Primary Criteria

1. How is Infertility defined and what are the medical indications required for an ART ?

2. What is the upper age limit for ART treatments ?

3.What type of Marital status is allowed generally for ART treament?

4 What are the Assisted Reproductive treatments covered.

a. Is an IVM allowed
b. Is PGD allowed
c. Is Assisted Hatching allowed?
d. Is sperm donation allowed?
e. Is Oocyte donation allowed?
f. Is Embryo donation allowed.

5. How many cycles of the treatment is generally allowed?

6. How many embryo transfers are allowed ?

Section B - Additional Criteria

7. Tests generally allowed

8. Diagnostic procedures alllowed

9 Non surgical treatments allowed

10 Infertility surgeries allowed

11. Additional services covered

12 Artificial insemination covered

13 Policy medical conditions for each treatment (Medical Indication)

14 Exclusions

Ppractitioners' expectations of coverage from an ART insurance policy

All doctors felt that insurance company must cover these treatments. They rebuked at both the justifications given by insurance companies for not covering infertility - that the treatments are experimental and hence not covered and that infertility is not a disease. Few doctors felt atleast the insurance company should cover the treatment cost (drugs, injections, scans) etc and things such as consultation and diagnostics can be borne by patient. But many believed that , from diagnositic tests till post treatment should be covered since diagnostic such as laproscopy is very expensive. Majority of them felt that Consultation does not cost much and can be borne by the patient herself.

Bursting the myth - Infertility treatments are not covered in India by Insurance companies

It's a myth that infertility treatments is not covered by insurance companies. All insurance companies representatives agreed that , even though they have stated ART as exclusion in all health policies - they are forced to cover it under group insurance policy. Even public sector companies do cover these treatments with a sub limit. In the words of an Insurer *'The Corporates demand that it should be covered. We have no other choice but to cover, even though it is an exclusion. If we dont cover we lose the business. The premium we receive from them is very high. '*

The rich gets the cover - The poor does not

Repeatedly all the insurance company experts said they are forced to cover as they will lose business if not covered. But as far as their principles go, they feel it should not be covered in the first place. But the rich have a better bargaining power and so the insurance companies listen to them , while the poor dont and neither do they ask, so they

are not covered. Some insurers also admitted, that while sanctioning the claims, they go through a feeling of guilt. *'On one side I am approving a claim of lakhs of a person working in corporate who I know can easily afford the treatment despite the treatment being an exclusion, and another side , I reject the claim of a poor fellow for 1000 Rs. because it is an exclusion . I feel very sad when I see that. I feel like approving his claim , but I cant my hands are tied'* Thus , it is the same market, same insurance company , but a rich gets the cover and poor does not .

The status quo

Currently the cover is available only for corporate and public sector employees under group health policy . Very few private companies have started coming up with these policies , however, so far no reported claim has been settled. The companies covering dont have much information and thus have limited their sum assured to 50,000 per year. Upon interviewing the insurance company's manager , it was found that the policy is at a nascent stage and so , it is not completely developed. Upon reading the prospectus, it was found that neither the covers, conditions or exclusions were sufficient. Thus the market largely stands uncovered. As per IRDA infertility treatments are an exclusion and hence they need not be mandatorily covered. It depends on companies if they wish to cover it or not.

The reason for resistance in covering infertility treatments

Presence of Moral hazards, Past bad experience with Health Insurance and a belief that infertility is not a disease is what stops them from issuing policies covering infertility treatments. All people interviewed felt there was a very likely moral hazard threat from the hospitals side. While they spoke with conviction about their moral hazard belief, what surfaces out is the bad experience they have had in settling health insurance claims. Either , the tests were unnecessary or the treatment cost inflated. If insurance is provided for infertility treatments , hospitals would hence forth go for IVF at a drop of a hat without even considering the chances for natural conception is what they feel. In the words of an insurance expert who comes with more than 25 years of her association in the Insurance industry ' *As a lady I wish there were policies of such sort , but as an*

Insurer its a 'No' I am afraid this cover will increase the cases of infertility treatments. I believe most of them are voluntary infertility cases. Technically, the policy if designed should cover only those who have tried everything and are not able to conceive naturally and the genuine cases. . A lot of what the insurers feel come from their experience. For instance a very senior insurance specialist points out '*As an insurer, I will not encourage this policy as I feel hospitals will take advantage of this. Even if patients can give birth naturally by waiting for couple of years , hospitals will encourage for ART I feel. Ceasaran is an example. Even if mother can give birth naturally, many doctors advise C-Section'* Keeping the bad experiences apart even if they wish to incorporate a new product for the benefit of the needy, the companies poor financial health does not permit. The public sector feels health is already a bleeding portfolio - full of high claims and less premium base leading to losses. In this situation to come up with a new product of such sort with less takers and high moral hazard is a risk. Private sector insurance companies are comparitively more receptive but that could also be because they are just a decade old in the market. But they too are of the opinion that moral hazards are high in health from the hospital side. One more reason for not covering the infertility treatments is that they dont regard infertility as a disease. In their own words' *We dont regard pregnancy as an ailment.'; Child birth is not a disease. It is a gift to the parents'*. They have a completely different perspective of a disease which should be covered. Any thing that is life threatening, which makes survival of a human being difficult is a disease and insurers should be covering it. The physiological malfunction of the reproductive organs makes a mother infertile but their own health is intact and hence it need not be covered. They have a practical view towards this problem and all unanimously said that in a country like India where population is high, this product is not needed. Thus , in a way pointing out that Insurance products should help the country at large and not be a detriment. Perhaps that is also a reason for IRDA calling such treatments as exclusions.

The way out - Solutions on designing a robust framework (Insurers perspective)

Even though, as insurers they felt to incorporate such an idea is a difficult proposition, as human beings each one of them empathized with the problems faced by infertile couples and all wished there was a product of such sort. Especially ,with regard

to women from lower strata of the economy , who due to any infection is not able to conceive. In their words - *In my opinion ac cover can be designed and restricted to lower middle class and poor people who have infections and diseases because of which they are not able to conceive. A woman who is not able to conceive especially from a lower strata goes through lot social problems.* .Even from the purely business point of view few experts felt it was the need of the hour . As a respondent points out ' *Many people suffer from infertility and ART is in big demand. With the increase in the market for ART, insurers may now look at introducing a suitable product.*

As per the conversations with them , if the following things were taken care , a product can be brought out in the market.

1. Incorporating high Copay and sublimits for each treatment so as to make the Insured accountable . Consequently the insured would question the hospital about a test or treatment prescribed in case any thing was unnecessarily prescribed. This would take care of the moral hazard.Also to have a high premium so as to ensure that the portfolios dont incur losses.

2. Having a clear MOU with the empanelled hospital about the treatments that can /should be covered. In their own words ' *Technically, the policy if designed should cover only those who have tried everything and are not able to conceive naturally and the genuine cases.* For this they needed an exhaustive study to be done on what is relevant, needed and should be covered.

3. Clear conditions such as number of years as waiting period , treatment in approved hospitals only covered, number of cylces to be covered, list of exclusions .

4. Having a clear understanding of the basic sum insured calculation and there by depending on the geographical location and the type of hosptial and standard of living of the insured to calculate the final sum insured.

5. Having less or no promotion for this product. Since , the risk of moral hazard increases the more the product gets promoted. Not involving hospitals in client service or

promotion and by selling these products only through reliable insurance professionals who identify the right individuals and sell the policy.

6. Having the right tie ups with genuine empanelled hospitals and T.P.A's ,

7. Selling the products as an add on cover and through underwriters office only and not through any other channel.

8. To start providing policies for the weaker section of the society since infertility is a social stigma and affects women adversely. Thus Government should help insurance companies. In the words of a respondent ' *Government should provide a kind of subsidy to economically weaker sections for taking this kind of treatment so that such segment may look for this policy.*

' Government can have a network with hospitals where the treatment can be given at a standardized cost. Government can choose primary health centers for this task and government can keep an eye on the treatments and in someway the doctors, insurance companies and government takes financial responsibility for such treatments. But with a condition that , Government should do strict monitoring of hospitals. Otherwise , if allowed the product will become more sought after and then finally insurance companies have to bear the losses'

9 A strong support from IRDA to promote such products . In their own words ' IRDAI may also provide approvals for this kind of policies on pilot project and provide encouragement to the insurers promoting this product.'

10. On Building the right value proposition and the business model, Insurers believe that such a framework be built with a service motive. Since Insurance itself is built on principles of service. However, at all times keeping the company safe from moral hazards and losses. In their own words *' This is more on service side. You should think of getting all stakeholders together and helping the needy but ensuring no one is at a loss. For the upper middle class people, if this product is sold, it should have higher premium and higher copay.* With Government support and bringing these activities under the CSR ambit the framework will be success.

The Proposed ART Framework

Introducing the Framework

The proposed framework has been drafted for Insurance Companies and Government to draft policies and schemes so as to make infertility treatments affordable for women who are in need. Findings from research questions 1 to 7 form the base for this framework. It is solely made keeping in mind only infertile women and thus ART for male factor is out of scope of the study.

Health Insurance Values as a base for the framework

The four principles of health insurance namely -Equity, Solidarity, Risk pooling and Community empowerment is the backbone of this framework. In a country like India there are many economic disparities. While a rich can afford to buy insurance benefits for his needs a poor is not able to. But right to health is an equal right for all the citizens. Equity is strengthened when each one pays according to his own ability. It is indeed difficult to practice equity without the sense of solidarity among people. Thus, routing insurance through associations and unions where there exists camaraderie between people belonging to same set of values work. (Devadasan 2006) All brothers and sisters of the same country as a community must wish for strong empower

ment of all communities- men and women, rich and poor ,old and young , healthy and sick. Risk pooling is improved when risks are distributed among large numbers with an underlying sentiment of helping each other as a community when in need.

Principles guiding the framework

Child Birth a Birth right- Every citizen has a right to give birth to a (one) child. If , due to certain circumstances, an individual is not able to give birth to a child, community must take responsibility to help the individual.

Involuntary Infertility - An individual who voluntarily postpones child birth has become infertile by going against nature's wish and the framework does not intend to support them.

Technology for all - A good technology such as ART must be used to serve the community and should not be a privilege for the chosen few

No Multiple policies - It is the normal tendency of insureds to buy insurance from two companies to receive luxurious coverage. This also increases their bargaining power. They receive additional benefits too. In the long run , the product may become unafforable to the poor. Thus , double insurance should not be encouraged.

Assumptions

(Factors kept in mind while building the framework)

Insights gained through this study (both interviews and literature) are the guiding light for bringing out the solution (framework) to the problem of lack of insurance coverage for infertility treatments.In other words, all that was quoted by the insurance companies as reasons for not being able to cover infertility treatments have been kept in mind while drafting this framework.

a. Anticipation of huge losses due to poor premium collection and increase in incidents of infertility treatments.

b.Moral hazards from the supply side ***(refer 9.1 interviews with insurers)***

c. Adverse selection from patients (receiving calls after the age of 32 more) ***(refer 9.1 interviews with insurers)***

d. Universally Low success rates of IVF which may raise incidents of repeat cycles ***(Smith, 2015)***

e. Difficulty in selling infertility risk proposition to the buyers there by decreasing the premium base.

f. Non consistent premium payment from the Government side. ***(Rai ,2019)***

e. Public sector insurance companies are forced to wave off exclusions such as ART for big corporations owing to the large chunk of premium received ***(refer 9.1 interviews with insurers)***

d. Structure of Mediclaim policy for the purpose of creating coverage (Max limit to be paid) has been considered, as it has been considered as a robust health insurance product in the market. (with sub limits) ***(refer 9.1 interviews with insurers)***

Scope and Usage

The framework is a guideline to help policy planners (IRDA, Government, Insurers) to develop health insurance plans .

Women are the beneficiaries of the framework and only IVF has been identified as a treatment for coverage under this framework.

Population Strategy

It is almost impossible to reach out to all the sratas of the entire population .Thus , it is better to first start the pilot with the organized sector and then slowly move towards unorganized sector. People working in an organized sector are easily reachable through their employer. However, people from unorganized sector are not easily reachable. Another thing to be kept in mind is that , not all individuals require insurance in the same way and magnitude. Every strata's needs are different. Needs are more or less based on what the income/earning capacity is . Employees State Insurance Act has used a benchmark of 21,000 Rs as a monthly wage and this has been so far the most consistent bench mark Looking at the current scenario the following community groups can be formed based on the insurance coverage and their economic strata-

1. Women below poverty line
2. Women who are unemployed or self employed and whose family income is < 21,000 Rs.
3. Women who are employed and have an income under < 21,000 Rs and are covered under ESI

4. All Women whose family income is > 21,000 , who are either working individuals ,who are self employed ,or unemployed and who do not have an insurance cover for ART .

Selection of Beneficiaries

From the four categories (1-4 mentioned above), women below poverty line and women covered under ESI need not be included to provide coverage. The rationale for not selecting women falling under ESI is that , they are covered under ESI and ESI has started offering infertility treatments, particularly IVF.

The reason for not including women under poverty line is a rather crude and yet practical one. Women , who fall under this category , hardly earn Rs. 1500 per month. It is difficult for them to make two ends meet. Not including this strata in any manner is not because of their high fertility rates , nor it is because of the fact that Government funds can be routed for improving their living conditions such as Health, Water, Sanitization. It is because of a sheer concern , that due to their poor financial condition and hard life they may not be able to endure the IVF journey. However, to include them too should be looked into in the long run. Infact , a different scheme should be introduced only for this category , so that their overall Reproductive health is protected free of cost.

The proposed framework will be best put to use by pooling the risks of category 2 and category 4 ie. Women who are unemployed or self employed and whose family income is < 21,000 Rs. and All Women whose family income is > 21,000 , who are either working individuals ,who are self employed ,or unemployed and who do not have an insurance cover for ART .

The rationale for pooling in their risks together is explained in the forth coming paragraphs .

Definition of a Woman as a Beneficiary

'Woman' within the context of the proposed framework is a Married Woman

The fact that single women should also be given a right to use Assisted reproductive treatments is acknowledged , however single woman and woman in a live in relationship are not included .One of the reasons for designing this framework is to help those women who face social stigma of being infertile and subsequently it affects their health. Naturally, single women dont fit into this reason. Thus they have been excluded from the purview of this framework

Definition of Infertility

Infertility is defined as failure to conceive naturally after having regular intercourse without the use of any contraceptive for one year ' (Source - WHO)

Findings, section 9.4 indicate that this 1 year may be more for those married couples who due to their work requirements dont stay together for eg. Husband working in Chennai and Wife working in Bangalore. Also, if a woman is already above 30, for them they need not wait for a year to start the infertility treatment. Six months of regular intercourse also some doctors have suggested to be considered for diagnosis of infertility .However, to prevent adverse selection and avoid deliberate delaying of conception, minimum of one year time period is suggested

Is infertility a disease?

According to WHO , Infertility is "a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse."… (WHO-ICMART glossary[1]). Besides this , all the doctors through interviews are of the staunch opinion that infertility occurs due to physiological malfunction and infertility can also subsequently cause mental illnesses in a women for fear not being accepted by society.

Thus Infertility is a disease which should be covered by Insurance companies , just as the way other diseases are covered

Role of Community in battling infertility

One must understand that Infertility can arise either due to occupational hazards, life style diseases and also due to infections. The concept of reproductive choice must encompass policies that make it possible for couples to aspire to have the number of children they wish. ***Tabong etal (2013)*** We live in an eco system where all of us are interdependent on each other. For eg. A Teacher teaching in a class is dependent on a worker who makes chalk in a factory. An Actor is dependent on a hair stylist. We cannot isolate infertile people by thinking that it is their own problem. To some extent we can

make the factories who pose occupational hazards responsible but ultimately, these factories too manufacture things which are benefitted by the whole community.Somewhere , whatever may be the cause, we must learn to believe that infertility is a community disease, which spreads quickly and widely and affects slowly the whole community. Thus , Community plays a role here in making lives of infertile women easier , by helping them with treatments , encouraging them and motivating them to live life the fullest. The usual norm of asking a Women a year after marriage, what about kids should be discorouaged. This puts unwanted pressure on the couple and has an adverse affect on the Woman.

Assisted Reproductive Technology Treatments and Rationale for selecting only IVF for the framework

Five Assisted reproductive technology treatments are used to treat patients suffering from infertility- IUI (Intrauterine Insemination) IVF (Invitro fertilization), ICSI (IntraCycoplasmic injection) , ZIFT(Zygote Intrafallopian transfer) and GIFT (Gamete Intrafallopian transfer)

IUI is not covered under this framework because IUI is predominantly used for male factor infertility . IUI is also used in very few cases related to female infertility such as issues related to cervix. But since an IUI procedure does not cost on an average more than 25,000, it is best borne by the insured themselves. If IUI is covered, infertile males also will reap the benefits of the schemes, which primarily is not the objective of the framework.

ICSI has also not been included in the framework. Rationale for covering ICSI is that ICSI has been more successful and useful in cases of male fertility. Even though doctors do prescribe ICSI or ICSI with IVF incases of unexplained fertility, it is still out of the ambit of this framework . Thus it has not been included. (Boulet et al) (cause the framework aims to address patients detected with female infertility only). GIFT and ZIFT need not be covered as it is not being practiced by clinics. (refer 8.1 Doctor interviews)

It may be noted that including only IVF for coverage is predominantly from the operational point of view , making life easy for the Insurer. Also as previously mentioned, only female infertility cases is the emphasis of this project. There is no disagreement to the fact that Doctors may use IUI and ICSI too for treating the female infertility cases (as some doctors say so), however, for a pilot insurance project of such sort, IUI and ICSI has been dropped.

Designing the cover - Add on/ Inbuilt/Standalone product

Of the three propositions of Add-on, Inbuilt and Stand alone product, Add on is clearly the Insurers choice . It completely mitigates the risk of not getting enough buyers for the product and also it is easy underwrite . By incorporating various sub limit options, the risk may not be high. As per insurers add on is safe . The need for the product is not yet established in the market so to venture into a proposition of an add on under all existing health policies is recommended.

Standalone product may not have enough buyers . Also to convince people to buy such a product by informing them about the happening of this event in near future (to tell someone that they may become infertile in near future) is difficult. However, all Insurers agreed that in few years with rising infertility issues , standalone products will become the need of the hour . (refer 9.1 insurer interviews)

Inbuilt feature is not recommended as not every one will require it . For eg. It is an absolutely useless feature for a couple with two kids who wish to buy a health insurance policy For them the inbuilt cover of infertility treatment is waste of money.

Difference between the beneficiary groups

As previously mentioned the framework intends to help two beneficiary groups - Women with low family income (less than 21 ,000 Rs) and Women with higher family income (more than 21,000 Rs)

Both the set of beneficiaries are different, While the former lacks insurance facilities, does not have knowledge of insurance schemes , come from a lower middle

class background and dont postpone conception. The latter on the contrary , is aware about insurance schemes , may consist people from upper middle class and may belong to a family which is career oriented and thus may postpone conception. Another distinct factor which differentiates both the beneficiary groups is their physical health. It has been observed that , upper middle class and high income level women are obese and are prone to lifestyle diseases which also contribute to certain causes for infertiltiy. On the other hand, women from less income groups get poor nutrition, does not have enough immunity and are prone to infections such as Tuberculosis which eventually turns in to infertility. The last distinction happens due to their capacity to pay premium and bargain an insurance product.

Designing the risk pool

With the diverse nature of beneficiary groups, should both the groups be covered together or should they be covered separately is a question that surfaces.

The problem in separating the beneficiaries and designing separate products/covers for both of them is that we may not be able to capitalize on large numbers. The premium base will be small. Also, though they are different in many ways the risks are balanced. While one category may suffer from infections, the other may suffer from lifestyle diseases. Amongst their diversity one strong commonality is that they all are women and of the same reproductive age group. The proposed framework further also suggests getting funds from Government for paying premium for the lower income group . In case of delays in disembursements of funds from government or the model for some reason faces challenges due to lack of funds, because of the premium received from higher income groups , the model will still remain sustainable. Thus both the beneficiaries should be in the same risk pool.

Proposed Solutions

Two solutions are proposed -

1. A standalone product for the benefit of all women - including both low income beneficiary group and high income beneficiary group .This can be rolled out on pilot basis with the help of IRDA (using the framework suggested below)
2. To add the feature of IVF coverage under mediclaim and other health policies and roll out a pilot with the help of IRDA. (using the framework suggested below) .

Value proposition

- For Stand alone product (ie Women of low income groups and high income groups)

To provide a complete insurance coverage for women suffering from any reproductive diseases that may result into Infertility at a later stage in life and to provide cover for women who wish to go for IVF treatment . Maternity benefit is not covered.. (See the list of reproductive disorders mentioned in the coverage that may be covered.)

- For Add on cover (To all health product buyers)

To provide additional coverage to people who would otherwise go for a health policy where ART would be an exclusion. All reproductive diseases would be covered in the health policy and thus this add on cover should specifically cover IVF only. Thus the underwriting aspects will differ. The minimum and maximum age of entry and term can be the same as mentioned in solution 1 ie stand alone product.

Term and Age

For both the solutions - Keeping in mind the average reproductive age of women (18-35) the Minimum age of entry may be fixed as 18 and Maximum age of entry can be fixed as 32. The reason for not extending the age of entry beyond 32 is to avoid adverse selection and also the fact that keeping in mind the waiting period of the programme by the time ART starts women would have crossed the age of 36 where the chances of success become less

Implementation (Solution 1) (Stand alone product for women of low & high income)

Below listed points and Figure explains Solution 1 and its components in detail.

Table : Insurance Coverage Framework for Assisted Reproductive Treatments for Women

Serving Entity → / Role ↓	Organizer (NGO/Trust)	Hospital	State Government	Corporate entities	Insurer	IRDA / Indian Medical Association	LIG	HIG
Beneficiary	×	×	×	×	×	×	✓	✓
Assistance and Support to Lower Income Group (LIG)	✓	✓ (treatment)	✓	✓ Voluntarily	✓	×	×	×
Assistance and Support to Higher Income Group (HIG)	×	✓ (treatment)	×	×	✓	×	×	×
Premium contributor	×	×	✓	✓ Voluntarily	×	×	✓ (50%)	✓ (100%)
Premium Collector	✓ (from LIG)	×	×	×	✓ (From LIG & HIG)	×	×	×
Facilitator	✓	×	×	×	×	×	×	×
Monitor	✓	×	✓	✓	×	✓	×	×
Indemnifier	×	×	×	×	✓	×	×	×
Enroller of Hospital	×	×	✓	×	✓	×	×	×

Defining the components of the framework

LIG /HIG -Read Definition given under 'Selection of Beneficiary section' under page number 65 and 69

Organizer

Organizer can be a Non Governmental Organization, A Trust or a Gram Panchayat. Organizer is the coordinating link between State Government Corporates and other entities who wish to voluntarily contribute for the benefit of low income groups. Since

these women cannot afford the entire 100% premium, the organizers can create a fund with the help of state government/Corporate contribution and the insured's own contribution. Thus 50% premium is paid by insured and 50% by Government or Organizer created fund. The organizer is incharge of the collected fund. This entity pays premium to the insurance company and the insurance company issues the policy for all the beneficiaries. The organizer performs a role of a guardian to the low income women beneficiaries , educate them from time to time, and ensures both insurance companies and hospitals serve these women without any differentiation ***.(National Rural Health Mission report)*** Periodically the entity also reports to IRDA and State Government, and Indian Medical association about the work of hospitals and insurance companies. Organizers role is limited to only low income group, for the high income group, they themselves will liase with the Insurance companies. They pay full 100% of the premium.

Insurance Company

Insurance companies are indemnifiers and they cater to both the income groups by issuing policies to them and indemnifying them when need arises. Insurance companies receive premium from Organizer for low income groups and from higher income groups (HIG women pay 100% premium to Insurer directly) Insurance companies empanel the hospitals along with the State Government , provide insurance to both the set of beneficiaries without any differentiation and settles claim of hospitals. .

State Government - Responsible for funding 50% premium for LIG women, empanelling the hospitals, monitoring the organizers functions. Guiding Insurance companies , Hospitals and promoting this scheme from time to time among general citizens.

Hospitals

Serve both beneficiaries without any difference .

Corporate entities

They can contribute any fund possible to the organizers on a voluntary basis.

IRDA -

Monitoring the insurers to ensure smooth functioning of the framework

Indian Medical Association

Monitoring the hospitals to ensure smooth functioning of the framework .

Implementation of the Framework

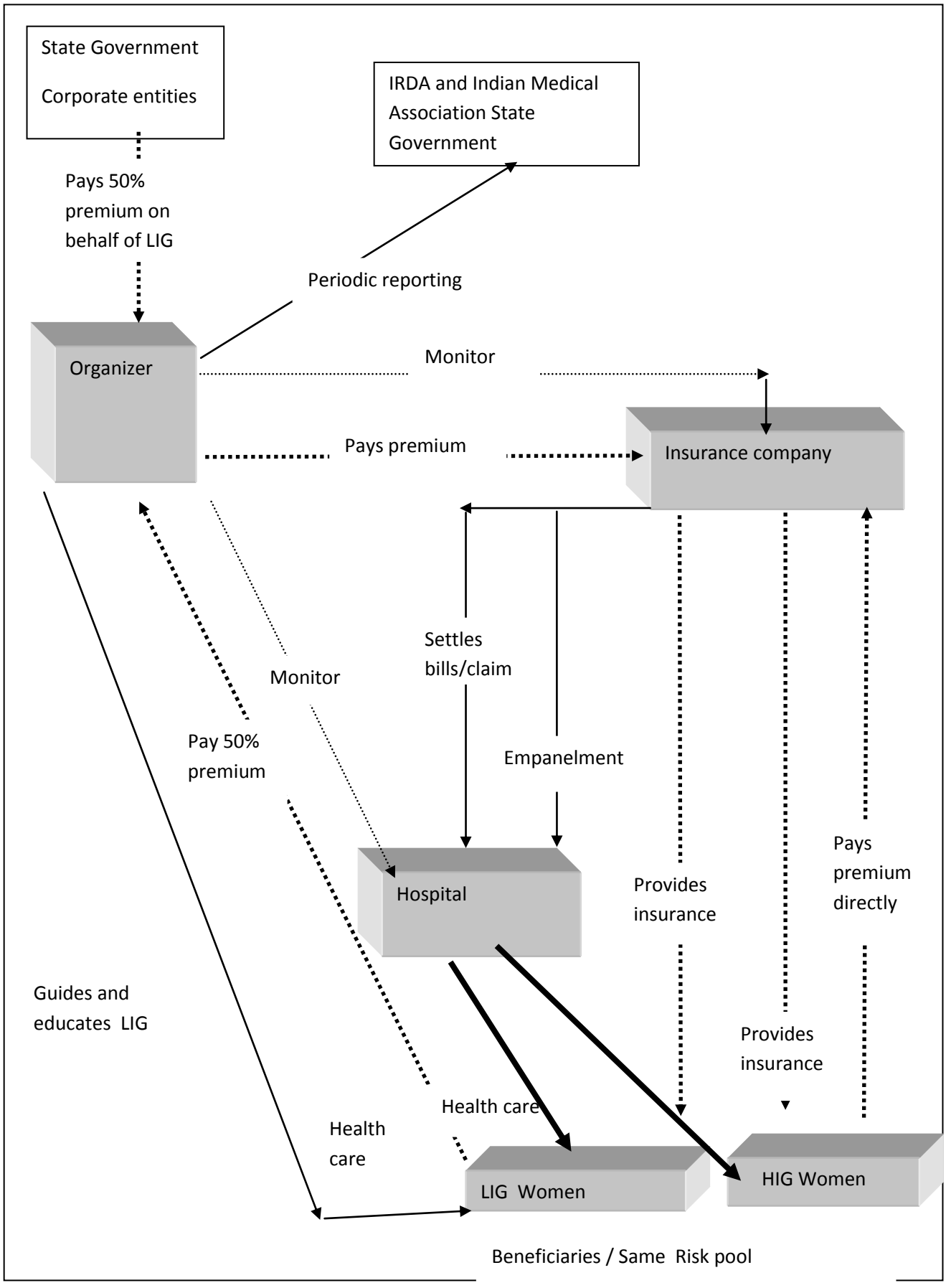
- Under the pilot stage one IVF cycle can be covered and going forward two cycles can be covered.
- Ideally number of embryos to be transferred can be age less than 30 less 1 embryo and more than 30 , 2 embryos. following the Australian model (refer finding 10.2). This will take care of risks due to multiple births. But , since doctors have been following the current practice of implanting 2 embryos to increase success rates, insurers may consider the same too. This point is debatable.
- Of the stages of Consultation, Tests, Diagnostic Procedure, Treatment, Inpatient, Post Treatment- all stages except for Consultation should be covered.
- The Inpatient is a Day care procedure of Half a Day only. Thus the sum insured limits which usually depends on room rent does not apply for IVF treatment.
- In the pilot phase the Insurer can follow the reimbursement method and later on the Cashless method is recommended.
- The best way to decide the sum insured is to determine the minimum and maximum cost of IVF considering the city the patient resides in and there after letting the insured decide the sum insured amount. For instance - The sum insured can be anywhere between Rs. 1,00,000 to Rs. 2,000,00. And the insured can decide to chose whether he wishes to chose the 1 lac sum insured or 2,00,000 sum insured. Thereafter , copayments percentage and sub limits for each category /item of treatment can be set. For eg. for a sum insured of 2,00,000 Rs. sub limit for Tests 10,000, for Diagnostics 50,000 for treatments 1,20,000 , Inpatient 10,000 and Post treatment 10,000 can be set. Refer the sum insured determination section to understand a rough estimate of costs under each category.
- Transportation costs -On an average , as per the interviews a patient during the tenure of IVF procedure visits the center for tests , consultation etc for 10 times. Though it depends on case to case and also variation in treatments. These costs can also be indemnified.
- Loss of wages -Patients either take leave and come from office, or they are escorted by their spouse /father/mother etc, thus indemnifying a day's wage would also be preferred.

Determination of sum insured

On an average an IVF will cost anywhere between 85,000 Rs and 2,00,000 Rs. After taking the average costs of IVF for 15 cities in India , the median cost comes to Rs. to 1,30,000 . The highest cost of an IVF is in Chennai and the lowest in Indore.

To arrive at a sum insured of the policy and to decide the sub limit of tests, diagnostic procedures, non surgical treatments, infertility surgery, treatment charges , the following cost/service sheet can be used for reference. The following has been prepared in consultation with senior doctors . Most of the doctors agreed to the below ones . Hospitals were not ready to provide the costs during the interview. But one grey literature source (a brochure of a famous hospital was found) through a known source and thus has been used here. These are mere indicative and there may be differences from one hospital to another.

Fig 4-Schematic representation of the framework



Most prescribed tests, Procedures, treatments, surgeries, ART , Normal IVF Package and Add on

Table Most Prescribed Tests

Sr. No	Name of the Test	Cost
1	Testing for viral status (HIV, hepatitis B, hepatitis C)	700
2	Follicle-stimuating hormone [FSH],	800
3	Luteinizing hormone	700
4	Human chorionic gonadotrophin	N/A
5	Prolactin	700
6	Thyroid stimulating hormone	500
7	Karyotype testing*	N/A
8	Embryotoxicity assay*	N/A
9	Serum inhibin B measurement (value in assessing ovarian reserve is uncertain)*	N/A
10	Home pregnancy tests and home ovulation test kits	500

Table: Diagnostic Procedures

1	Endometrial biopsy	N/A
2	Hysterosalpingography (hysterosalpingogram (HSG)	2150
3	Hysteroscopy	23,000
4	Laparoscopy and contrast dye	25,000
5	Ultrasound (e.g., ovarian, transvaginal, pelvic)	N/A
6	Monitoring of ovarian response to ovulatory stimulants (Estradiol , FSH , HCG , quantitative , LH assay, Progesterone , Serial ovarian ultrasounds	N/A

Table :Type of Infertility Surgeries mostly used

Sr. No	**Type of Infertility Surgery**	**Cost**
1	Hysteroscopic or fluoroscopic tubal cannulation	23,000
2	Laparoscopic cystectomy	25,000-50,000
3	Fulguration of endometriosis implants plus adhesiolysis	22,300
4	Removal of myomas, uterine septa, cysts, ovarian tumors, and polyps	10,000
	Total cost of infertility surgery	68,460

Table :Non Surgical Treatments

1	letrozole (Femara)	2,300
2	Lutropin alfa (Luveris)	4,000
3	Metformin (Glucophage)	N/A
4	Oral clomiphene citrate	N/A

Table :Assisted Reproductive Treatment

Sr. No	**Assisted Reproductive Treatment**	**Cost**
1	IVF	85,000 to 2,00,000 (Depending on the city)
2	Frozen Embryo Transfer	26,500
3	Assisted hatching	18,000- 25,000
4	Cyropreservation of oocytes	N/A

Table : Additional Services

Sr. No	Additional Services	Cost
1	Gonadotropin releasing hormone (Injectable Medication)	N/A
2	Goserelin (Zoladex)	N/A

3	Leuprolide (Lupron)	N/A
4	Human menopausal gonadotropin	N/A
5	GnRH antagonists (ganirelix acetate (Antagon)	N/A
6	GnRH antagonists (ganirelix acetate (Antagon)	N/A

A normal IVF package

(offered by a particular hospital for Rs. 85,000 include the following)

- HMG – Dose 225 to a maximum of ten days
- Antagonist – Maximum of four days
- HCG – one dose
- E2 – three times only
- Progesterone - 2 times only
- Follicular study for running cycle
- Stimulation consultation
- Egg retrieval charges
- OT fees
- Anaesthetist charges for ovum pick up
- Day care bed charges
- Injection administration charges on working days

For the these things extra cost is charged - OPU and IVF charges And Embryo transfer 62,000, Embryo freezing costs (Up to 4 embryos) 15,000, Follicular scans 3000, Blood tests 7,000 Repeat cycle costs , Endometrium Preparation Medicines 10,000 ,Frozen Embryo transfer 26,500, Blastocyst culture cost is not covered in IVF treatment and usually it costs around 15,000 to 20,000 Rs .However, Insurers can try covering Blastocyst too as it will reduce the risk of multiple pregnancies **.**

Add ons

Tubal reversal Options, PGD/PGS Option, Freezing, Surrogate/Gestational Carrier , Frozen Donor Egg and Donor Embryo Package, Fertility Preservation Package, Genetic Testing.

11.20.8 Reproductive disorders that may be covered along with IVF treatment

(This list is put together by referring to list of Common diseases published by Center for Disease Control and Prevention. These are top global reproductive diseases. In the Indian context , no statistic could be found. Thus this one has been used.)

1. Endometriosis

2. Uterine Fibroids

3. Gynecologic Cancer (Cervical Cancer, Ovarian Cancer, Uterine Cancer, Vaginal Cancer, Vulvar Cancer)

4. Interstitial Cystitis

5. Polycystic Ovary Syndrome

6. Chalamydia

7. Bacterial Vaginosis

8. Genital Herpes

9. Gonorrhea

10. Pelvic Inflammatory Disease

11. Syphilis

12. Trichomoniasis

Determination of conditions

In the following conditions an IVF is usually recommended**. (Findings as per Research Question 2 and as confirmed with the Physicians.)**

1. Irreversible pathology of the fallopian tubes, resulting from an inflammatory process or from previous surgery.
2. Idiopathic infertility
3. Endometriosis
4. Infertility of immunological origin
5. Subtle ovulation defects
6. Defects in ovum pick-up
7. Defects in Gamete transport
8. Defects in tubal environment
9. Oocyte abnormality
10. Microsurgical techniques for tubal and peritoneal disease have failed
11. Already undergone tuboplasty and those with inaccessible ovaries
12. History of ectopic pregnancy,
13. Cervical factor
14. Ovarian disorders
15. Hypogonadotropic anovulation, oligoovulation and luteal phase deficiency
16. Luteinized unruptured follicle syndrome in polycystic ovarian disease.
17. Uterine disorders
18. Patients with Mullerian agenesis or congenital uterine anomalies
19. Women with severe intrauterine adhesion refractory to surgical lysis of the adhesion
20. Presence of peritubal adhesions , condition of the tubal wall, condition of the ciliary epithelium and degree of fimbrial damage would dictate the choice between IVF and microsurgery.
21. IVF may be offered for cervical factor only if repeated attempts (3-4) of intrauterine insemination have failed and other therapies have not resulted in pregnancy

Other Conditions

1. A clear explanation of why an IVF treatment is preferred over IUI should be stated and approval should be sought from the Insurance company before starting the treatment. There are chances that , an IVF is done eventhough through IUI it can be fixed. ***Bahadur & Homburg (2019).***

2. The claim will be considered only if IVF treatment has been received from a Tertiary clinic (Level 3) only. (ART ACT)

3. If found that a particular clinic has misused Preimplantation genetic diagnosis (PGD) for preimplantation sex selection then the contract with the hospital and insurance company will be terminated. Notice will be given to existing policy holders about black listing of the hospital. No claim shall be paid for any case found where the patient has tried to get help from PGD to known the sex of the child. This condition is put forth keeping in mind evils of PGD Kar et al (2018)

4. Male workup should have been done and the report should be attached prior to seeking approval for IVF treatment. This is to avoid cases where IVF is directly done without even doing a male Work up . Balasubramanium et al (2019)

Determination of Exclusions

Following exclusions have been framed after referring to insurance policy frameworks available outside India .Refer Resultsand Findings of Research Question number 2 Thereafter, they have been verified by Doctors.

Test Exclusions
Anti-mullerian hormone
Antiprothrombin antibodies
Endometrial receptivity testing
Uterine and endometrial receptivity testing (Endometrial function test (EFT) (cyclin E and p27) and E-tegrity)
Measurement of natural killer cell activity g. Reproductive immunophenotyping

Table 11.8

Non surgical treatment exculsions
Leukocyte immunization (immunizing the female partner with the male partner's leukocytes)
Dehydroepiandrosterone (DHEA)
FSH manipulation of women with elevated FSH levels.
Parenteral administration of lipids
Injectable medication exclusion
Human chorionic gonadotropin (hCG)
. Growth hormone for infertility treatment
Growth Hormone (GH) and Growth Hormone Antagonists
Drainage of ovarian cyst for infertility treatment
In-vitro maturation (IVM) of oocytes

Artificial insemination treatment exclusion
Double IUI
Direct Intra-Peritoneal Insemination
Fallopian Tube Sperm Transfusion
Intra Follicular Insemination
Sperm Precursors
Fees Associated With Donor Insemination
Cryopreservation Of Semen

Treatment exclusions
IVF cycles for the sole purpose of embryo banking
GIFT is considered experimental and investigational for person with male factor infertility or unexplained infertility problems
ZIFT with male factor infertility or unexplained infertility problems
Coverage of fees associated with oocyte donation, including recruitment and selection of donors, ovarian stimulation of donors, collection of oocytes from donors, and screening and storage of donor oocytes.
Routine use of oocyte cryopreservation in lieu of embryo cryopreservation, oocyte cryopreservation to circumvent reproductive aging in healthy women, and laser-assisted necrotic blastomere removal from cryopreserved embryos are considered experimental and investigational
Cryopreservation of embryos and oocytes (other than short-term cryopreservation of embryos that are necessary for contemporaneous use in infertile persons currently under active fertility treatment, or use of cryopreserved embryos or oocytes in women facing infertility due to chemotherapy or other gonadotoxic therapies) is not considered treatment of disease and is not covered.
EmbryoGlue
Partial zonal dissection (PZD)
Subzonal sperm insertion (SUZI)
Intra-cervical insemination or intra-uterine insemination [IUI], Clomiphene-citrate-stimulated artificial insemination (intra-cervical insemination or IUI), Electroejaculation , Donor insemination (Since policy is exclusively designed for women these are exclusions)

Physical hazards for the Insurer (Infections, Life style diseases and Occupational hazards)

1	Genital Tuberculosis
2	Polycystic Ovarian Syndrome
3	Celiac Disease
4	Chalmydia trachomatis
5	Obesity
6	Variations in Androgenreceptor
7	Heavy metal and pesticide exposure
8	Endocrine disruptors
9	Cancer treatment drugs such as Methotrexate
10	Lead, Certain ethylene glycol, Carbon disulfide (CS2),
11	M Genitalium
12	Ionising radiation, X-rays and gamma rays,
13	High biomass smoke levels, high emission factors, exposure to dust
14	Nutritional deficiencies

Identification of Target market and positioning for Stand alone and Add on

Target Market for Stand alone -

Women in the Reproductive age of 18 - 29 should be the ideal target group. After the age of 30 the chances of conception decreases and thus the success rates fall.

For Low income women , awareness can be done through organizers . The study also finds that, parents of daughters are the ones who are the most concerned particular

the Mother.(page number) It is being observed that they pay out of their pocket to get their daughters infertility treatment done. Awareness should be spread among mothers of teenage girls so that they buy the cover for the daughter. For High income groups , the promotion can be done through hospitals , Women's colleges, advertisements in Women oriented media.

Target market for Add on –

The insurance advisor should be able to look at the family who is buying health insurance and should identify those potential clients who may need an add on. People buying family floater policy and who have daughters can buy the policy . While selling health insurance products to newly married couple the feature can be highlighted . But only if they are married for less than a year. Else there is a potential risk of adverse selection

Positioning of these products

The greatest challenge of selling these products is that no one would like to believe that in the future they may face such a harsh event like infertility. Thus , product has to be positioned in the market as a complete protection from 'Reproductive diseases' for women.

Avoidance of Moral hazards and Adverse selection

Moral hazard from supply side

There was a great deal of apprehension found from the insurers side with regard to moral hazard from the side of hospitals. One way to ensure that this is curtailed is by making the patient responsible about the charges billed. Since, insurers settle all the bills, sometimes patients leave everything to the doctors . But if a copay is introduced, then in that case, the patient too would be thinking twice before going for the treatment.

Co-pay as a tool to mitigate Moral hazard

A copay of 50% can be introduced for IVF . This 50% should be on item wise ie - Test, Diagnostic procedure, Treatment etc. The company can design the best structure

after working out the premium. However, for all other reproductive diseases a lower copay is recommended

Sub-limit

Each category should have a sub limit and the copay is applied on the claim which falls below the limit. For eg. Sub limit for Tests is 14,000 Rs . Thus 7,000 will be borne by Insured and 7,000 will be borne by insurer. Assume , the tests cost 15,000 , the extra 1,000 will not be covered by insurer. Thus the insurer bears 7000 Rs. and insured bears 8,000 Rs.

Ideal Waiting Period

4 years waiting period is ideal for IVF and

2 years for other reproductive diseases.

Empanelment of Hospitals

The choice of the procedure to be used shall depend upon the need ,resources and circumstances of the individual couple, availability of the facilities, and experience and expertise of the Gynaecologist / Embryologist. The selection criteria for various ART procedures shall conform to the requirement as specified in Schedule I, Part-6.

Level 1 clinics do not require registration. These clinics can do the preliminary level of tests for infertility and can do certain procedures too as prescribed in ART act pg no14. They are not allowed to handle oocytes outside the body.

Level 2 clinics do require registration and they are allowed to do IUI and certain other procedures but they are not allowed to handle oocytes outside the body.

Level 3 - Tertiary level -Infertility clinics do require registration . In the words of the ART Draft these clinics have three functions to perform, viz., diagnostic and therapeutic at the highest level of specialization and with the best of facilities, and research (excepting on human embryos).Thus they are the right ones to perform all ART Treatments including IUI, IVF and ICSI. For level 3 clinic apart from the Gynecologist have a post graduate degree or diploma in Gyencology must also have the expertise of ovum pick up and embryo transfer. The hospital ideally can have a Andrologist, Clinical

Embryologist, and a Counsellor. However, they may be shared too. The hospital must have a programme director who takes care of the administrative affairs ,finance , and ensures the staff is well aware of the latest developments in medical science. During the registration of the clinic , a robust inspection is done by the health department checking the physical requirements such as the OT room, the laboratory and whether they have ready access to laboratories that can carry out immunoassays of hormones and various other tests. In the similar manner access to microbiology laboratory to carry out rapid tests is also essential. In case the hospital does not have a lab, it should be situated close to the hospital, so that patients can commute without any discomfort. The registration of these clinics is valid only for 3 years and hence the provider must check for the date in their registered certificate

Insurance companies must go for empanelment with only the level 3 (Tertiary hospitals only)

Empanelment of Organizers

Criteria for selection of Organizers

The role of an organizer is very crucial in such a programme. There is a need to have an impartial , unbiased, non opinionated , autonomous body who would ensure that the three stakeholders - Beneficiares, Health care providers and Insurance providers work in a smooth manner so as to serve the people. It is very important for the organizer to be an autonomous body. Their role is also to periodically assess the success of the programme, involvement of Insurance companies and hospitals and report to Insurance Regulatory Development Authority , Indian Medical Association and State Government periodically.

Who can be organizer of the programme -

- A trust
- State health corporation
- NGO's such as Samma

- An Association for women such as SEWA
- Educational Institutions especially the ones run for women
- Autonomous health care management related institutions such as Institute for Public health,Bangalore

Need and Role of Organizers

- Identifying the community of beneficiaries.
- Spread awareness among people about the programme. Especially to women and make them aware of the fact that government will be paying premium on behalf of them.
- Ensure Insurance companies market the product through proper channels and put up information on websites.
- Ensure funds from State Government and Large Corporations (CSR activity) is received for the set of beneficiaries for the payment of their premium and the same is credited to Insurance companies. Create and operate the fund as required from time to time.
- Ensure the health care provider provides services on time and in the most unbiased manner.
- Conduct an audit trail and review to keep a check on service quality and moral hazards and review the overall success of the programme.
- Ensure timely settlement of claims and proper efficient administration of programme such as putting development officers in charge of programme and putting proper compliance procedures in place.

Claim settlement process

One important aspect of claim investigation is to check the genuinity of claims. This requires medical expertise. Any test done without following it up with treatment should be investigated thoroughly.

Role of IRDA

IRDA has permitted the Insurance companies to make infertility treatments as a standardized exclusion. However, looking at the need of the hour and pain and suffering of needy people, IRDA may revisit their exclusions list. IRDA may take this framework on a pilot basis to see the response of insurers, beneficiaries and health care providers. Support and encouragement of IRDA is utmost crucial for the implementation of the framework.

Validation of Framework

The framework has been validated by a practicing Infertility treatment specialist. The Doctor has more than 15 years of experience dealing with infertility patients and is a Director of a reputed infertility treatment clinic. The advice was sought particularly in the following areas.

Non inclusion for IVF in the framework - As mentioned previously , the rationale for not including IVF in the framework was that IUI is of low cost and the Insured's can bear it themselves. According to the principles of insurance, it is best advised to make insured's bear small costs by themselves and the bigger ones to be borne by insurer.

Non inclusion of ICSI in the framework - The rationale for not covering ICSI under the framework is that this study predominantly focuses on infertility treatment coverage for women only. ICSI is predominantly done for male fertility and very rarely done for female infertility cases. The main objective of the study is to help women who cant bear a child due to their physiological inabilities and in turn becoming vulnerable to the society. Thus , ICISI has been kept out of scope of this study.

The tests commonly used, diagnostic procedures used, non surgical treatments done, infertility surgeries done, cover that can be designed , exclusions and general feedback on the work done.

Following were the Doctor's recommendations

Instead of excluding, IUI and ICSI for the framework, even these two treatments can be included for the coverage ,as it it will be comprehensive. ICSI is used to treatment female infertility cases too so ICSI can be included. However, keeping in mind moral hazard cases where few doctors may chose to do an ICSI instead of IVF since insurance coverage is available, it is fine to go ahead with IVF only framework. She infact also felt that , because of this policy framework, doctors may switch to IVF as the first step of treatment instead of suggested ICSI directly.

Limitations of the framework

1. Technically all ART treatments should be covered, whether it is female or male infertility case. Due to lack of understanding from the medical field, there may be many instances where IUI and ICSI is used to treat female infertility cases. But from a practical stand point , and with an intention to atleast start a pilot product IVF looks to be ideal. The only worry is that , hospitals should not skip IUI and keep suggesting IVF , just because IVF is covered.

2. The proposed framework prescribes designing a policy that can cover reproductive health diseases along with infertility treatment. Whilst a detailed study has happened on infertility causes and IVF treatment, for other reproductive diseases no such information has been provided (except a list of reproductive diseases to be covered) It has been presumed that the insurers would be having statistics on such diseases, as they have been covered under other health products.

3. Costs provided may vary from hospital to hospital.

Recommendations for further study

- The solution given as per this framework is restricted only to IVF and to reproductive disorders. A greater in depth analysis of reproductive disorders can be undertaken to make the framework more robust.
- Ways to bring in IUI and ICSI under insurance coverage, without ringing the moral hazard alarm can be taken up as a study so as to cater to diverse needs of people
- In future, a study can also be undertaken to provide coverage to patients suffering from male infertility.

Limitations of the study

Lack of knowledge of medical field and biological terminologies was an impediment during the study. Though, the data has been validated by doctors and no information has been comprehended by the researchers own knowledge (while reading medical terms), the lack of understanding of the subject may have caused unknown comprehension inabilities.

The framework is entirely based on the views of a small number of respondents (patients, doctors, insurers) and the researchers own knowledge and instinct . Due to the study's inductive nature, a wide range of possibilities and propositions have been proposed throughout the framework. Only by experimenting and testing each proposition over a period of few years, we will be able to understand what works best. Even then, for each company ,what works best will be different. Thus the framework has to be used as a guide and the insurance company must routinely do research to come up with good policies

Tentative Structure of Thesis

Chapter 1 - Introduction

(Introduction, Background of the study and Statement of the Problem)

Chapter 2 - Review of Literature

Chapter 3- Methodology

(Research paradigms, Research questions, Methods and Tools)

Chapter 4 - Results

(For each research question , data analysis would be shown seperately)

Chapter 5 - Findings

(For each research question, finding would be shown seperately)

Chapter 6 -Proposed Framework

(In detail the framework would be described)

Chapter 7 Conclusion

(This concluding chapter will summarize the thesis , throw recommendations for further

research and highlight the challenges faced and limitations of the study)

Annexure A

Sources used for Public funding, Clinics and Private insurers

The below listed tables indicate the final sources used to extract answers to research questions. The tables are presented in the same order of sources highlighting public funding art treatments, followed by sources used for drawing information about ART from clinics and hospitals that provide such financial products and finally private insurance companies who are into selling of infertility insurance products.

There is a variance in the display of tables owing to the nature of source.

Sources Used For Public Funding

Sl. No	Name of the article	**Citation**
1	Assisted reproductive technologies (ARTs): Evaluation of evidence to support public policy development	Alexa A Nardelli, (2014)[1]
2	Authority, Human Fertilisation and Embryology. March 2011. Fertility treatment 2014–2016 Trends and figures. UK : Human Fertilisation and Embryology Authority,	Authority, Human Fertilisation and Embryology (March 2011)[2]
3	ESHRE Central Office (European Society of Human Reproduction and Embryology). Comparative Analysis of Medically Assisted Reproduction in the EU: Regulation and Technologie	(Embryology), ESHRE Central Office (European Society of Human Reproduction and)[3]
4	Assisted reproductive technology: public funding and the voluntary shift to single embryo transfer in Australia.	Georgina M Chambers (21 November 2011)[4]
5	Funding Options for Assisted Reproductive Technologies in Developing Countries	Igberase GO (2016)[5]
6	The diversity of regulation and public financing of IVF in Europe and its impact on utilization	K. Berg Brigham (2012)[6]
7	International Committee for Monitoring Assisted Reproductive Technology (ICMART) world report: assisted reproductive technology 2003.	Karl G. Nygren, (June 2011)[7]

8	What's the message? A content analysis of newspaper articles about assisted reproductive technology from 2005 to 2011	L. King (2014)[8]
9	The long-term fiscal impact of funding cuts to Danish public fertility clinics.	Mark P Connolly (2011)[9]
10	The costs and consequences of assisted reproductive technology: an economic perspective, 2010	Mark P. Connolly(2010)[10]
11	Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review. Dublin Ireland : Health Research Board	Martin Keane, (2017)[11]
12	Public Financing of IVF: A Review of Policy Rationales.	Philipa Mladovsky(June 2010)[12]
13	Assisted Reproductive Technology Success Rates National Summary and Fertility Clinic Reports. Atlanta, Georgia, USA : National Center for Chronic Disease Prevention and Health Promotion , 2008.	Prevention (2008)[13]
14	Infertility in developing countries: funding the project	Sallam (2008)[14]
15	IFFS Surveillance Report 2013; International Federation of Fertility Society , October 2013 .	Steven J. Ory (October 2013) [15]
16	Illinois Department of Insurance. 2014. Insurance Coverage for Infertility Treatment. Illinois Insurance Facts. 1, 2014	Illinois Department of Insurance (2014)
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18	Regie de I'assurance maladie Quebec. Regie de I'assurance maladie. ramq.gouv.qc.ca. [Online] Government of Canada . http://www.ramq.gouv.qc.ca/en/Pages/home.aspx.	(Regie de I'assurance maladie Quebec)
19	Thiqa Insurance Program. The National Health Insurance Company - Daman . *www.thiqa.ae.* [Online] Daman Abudhabi . https://www.thiqa.ae/en.	(Thiqa Insurance Program.)

SOURCES USED FOR CLINICS/HOSPITALS FUNDING

Sl. No	Name of the Clinic/Hospital	Citation
1	ARC Fertility- USA	(ARC), A. R. (2019). www.arcfertility.com. Retrieved July 2019 , from https://www.arcfertility.com/arc-treatment-packages/
2	The women's (the royal women's hospital)- Medicare rebate is given by the Australian government	Hospital, T. R. (2018). www.thewomens.org.au. Retrieved july 2019 , from https://www.thewomens.org.au/patients-visitors/clinics-and-services/fertility-genetics/fertility-treatment
3	. CARE Fertility- UK-	CARE Fertility. (2006). carefertility.com. Retrieved 2019, from https://www.carefertility.com/
4	Create Fertility- UK	Human Fertilization and Embryology Authority, . (2010). createfertility.co.uk. Retrieved july 2019, from https://www.createfertility.co.uk/costs
5	First Fertility- Bangkok, Thailand-	First Fertility PGS Center Limited.,. (2008). firstfertility.co.th. Retrieved 2019, from https://www.firstfertility.co.th/packages/
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Sources Used For Private Insurers

Sl. No	Name of the Private Insurer	Citation
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2	Hong Kong Health Insurance- CCW Global	Hong Kong fertility Health Insurance, . (2018). CCW Global. Retrieved July 2019, from hk.ccw-global.com: https://hk.ccw-global.com/health-insurance/coverage/maternity/ivf-and-fertility-cover/
3	Illinois Law Mandating Insurance Coverage for Infertility- Illinois	Illinois, Illinois Law Mandating Insurance Coverage for Infertility-. (1991). InVia Ferility. Retrieved 2019, from inviafertility.com: http://www.inviafertility.com/faq/learn-more/illinois-law-mandating-insurance-coverage-for-fertility-treatment/
4	Progyny- smarter fertility benefits	Progny. (2019). Progny- Smart Fertiliy Benfits. Retrieved 2019, from progny.com: https://progyny.com/for-employees/redefining-fertility-benefits/

5	Medicare and Bupa Insurance (Australia)	Bupa Health Care,. (2019). Bupa health Care Organization. Retrieved 2019, from bupa.com: https://www.bupa.com.au/health-and-wellness/health-information/az-health-information/the-cost-of-ivf
6	PROCREA (Fertility)- Initiative by RAMQ- Health Insurance Board in Quebec, Canada.	PROCREA. (2019). Procrea Fertility . Retrieved 2019, from procrea.ca: https://procrea.ca/financial-guidance/ontario-treatment-coverage-payment-options/
7	Prosper Healthcare Lending- Infertility	Prosper. (2019). prosper fertility Organization. Retrieved from prosperfertility.com: http://www.prosperhealthcare.com/category/fertility/
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Annexure B

ART PUBLIC FUNDING DETAILS FOR 20 COUNTRIES-

Sr. No	Name of the Country	Public Funding status	Number of Cycles	For which Medical Indication	Age of woman	Marital status	Number of Embryos allowed
1	**Norway**	Public funding partial	Max 3	No Information	< 40 years	Married couples - Lesbians , singles not allowed	Single-embryo transfer preferred
2	**Switzerland**	No Public funding	No Public funding	No Public funding	No Public funding	No Public funding	No Public funding
3	**Australia**	Partial	No limit	Infertility	No age limit	Stable Relationship, Singles and Lesbians allowed	< 35 1 embryo >38 2 embryos
4	**Ireland**	No Public funding	No	Only the cost of drugs is covered	No public funding	Stable Relationship	No public funding
5	**Germany**	Public funding is partial (75% & 50%)	No info	Infertility	No age limit	Married Hetero sexual couples	No Limit
6	**Iceland**	Partial	No info	No Information	< 42 years	Marriage or cohabitation in law, Heterosexual couples	Not Specified
7	**Hong Kong**		Max 3	Infertility	No Information	Married couple	Max 3, 4-5 women >35
8	**Sweden**	Public funding partial	Max 3	Infertility or prevention of transmission of a serious disease.	< 45 years	Both hetero and homo couples, Stable relationship, lesbians and Single women	1 or 2 not more than 2

9	**Singapore**	Partial	One cycle	Infertility	No Information	Married Couple	2 embryos
10	**The Netherlands**	Private compulsory health insurance.	Max 3	Infertility or prevention of transmission of a serious disease.	< 45 years	No restrictions	Max 2
11	**Denmark**	Full coverage	Max 3 But may allow more if there are frozen	No indication needed	< 45 years	No restrictions	<40 2 embryos , > 40 3 embryos
12	**Canada (Ontario)**	Full coverage	One cycle	No, open to eligible patients with medical or non-medical infertility	< 43 years	No restrictions	Single Embryo transfer policy was established
13	**United states**	No Public funding	No Public funding	No Public funding	No Public funding	No Public funding	No Public funding
14	**UK England**	Public funding full and partial	Max 3	Infertility	< 40 years	No restrictions	< 39 1 worst case 2, > 40 2 embryos
15	**Finland**	Partial	Max 3	No indication needed	< 43years	No restrictions	Max 2
16	**New Zealand**	Full coverage	Max 2	Infertility	No information	No restrictions	Max 1
17	**Belgium**	Full coverage	Max six	No indication needed	< 43	No restrictions	< 39 , Max 3 embryos, > 40 no restrictions
18	**Liechtenstein**	No Information	No Information	No Information	No Information	No Information	No Information
19	**Japan**	Full coverage with copayments	Max 4	Infertility	No information	Married couple permitted	4 or more

		Partial				< 40 , Max 2 embryos , more than 40 , 3 or more allowed.
20	**Austria**	Max four,	Infertility	< 40 years	Stable relationship, Heterosexual	

PTO (other variables next page)

Sr. No	Name of the Country	IVM allowed	PGD	assisted Hatching allowed	Sperm donation	Oocyte donation	Embryo donation allowed
1	**Norway**	Yes	Yes	Yes	Yes	No	NO
2	**Switzerland**	No Public funding	No public funding	No public funding	No public funding	No public funding	No public funding
3	**Australia**	Yes	Yes	Yes	Yes	Yes	No information
4	**Ireland**	No	Not Used	Yes	Yes	yes	No information
5	**Germany**	Yes	No	No information	Yes	Yes	No
6	**Iceland**	Not Specified	Not Specified	Not Specified	Yes	Yes	No information
7	**Hong Kong, China (SAR)**	Yes	Yes	Yes	Yes	Yes	Yes
8	**Sweden**	Yes	Yes	Yes	Yes	Yes	No
9	**Singapore**	Yes	Yes	Yes	Yes	Yes	Yes
10	**The Netherlands**	Yes	Yes	Yes	Yes	Yes	Yes
11	**Denmark**	Yes	Yes	Yes	Yes	Yes	No information

12	**Canada (Ontario)**	Yes	Yes	No Information	Yes	Yes	Yes
13	**United states**	No Public funding	No Public funding	No Public funding	No Public funding	No Public funding	No Public funding
14	**UK England**	Yes	Yes	No Information	Yes	Yes	Yes
15	**Finland**	Yes	Yes	Yes	Yes	Yes	Yes
16	**New Zealand**	Yes	Yes	Yes	Yes	Yes	No Information
17	**Belgium**	Yes	Yes	Yes	Yes	Yes	Yes
18	**Liechtenstein**	No Information	No Information	No Information	No Information	No Information	No Information
19	**Japan**	Yes	Yes	Yes	Yes	No information	Yes
20	**Austria**	Yes	No	Yes	Yes	Yes	No

Annexures C

Analysis of Clinics/Hospitals Funding

Name of the Clinic	**Create Fertility, UK**
How it assists funding?	The clinic gives loans to patients who wish to undertake the treatment. For example if treatment cost is 9,984 . They take an initial deposit of 2,995, the loan amount is 6988 and the total repayment is 8372 which the patient can pay in monthly installments of 348 for 24 months or 582 for 12 months. This is for a treatment type of 3 cycles. For treatment type of 1 cycle the treatment cost comes to 3844 and the monthly installments for 24 months come to 134 and for 12 months 241.
What are the different packages?	The packages have basic coverage and additional charges for toppings Basic - Includes - monitoring scans, clinical advice, treatment plan consultation, egg collection, embryology, blastocyst culture, fresh embryo transfer, pregnancy blood test and early pregnancy scan. Toppings - with closed culture incubation (Embryoscope), IVM , HFEA cycle fee, blood tests (HIV 1, HIV 2, Hepatitis B core, Hepatitis B surface antigen, Hepatitis C, Luteinising Hormone, Oestradiol) and sedation by consultant anaesthetist., 3 egg collections, embryo freezing and storage for 12 months , pre-implantation genetic screening with Next Generation Sequencing (up to 4 embryos), 6 egg collections, 2 embryo transfers, ICSI Basic - Includes - monitoring scans, clinical advice, sperm preparation, insemination procedure, pregnancy blood test and early pregnancy scan. IUI - Toppings - 3 cycles, treatment plan consultation, Ovulation induction monitoring ,Embryo, Egg and Sperm Freezing, Frozen Embryo transfer procedure, FET after frozen egg thaw procedure with ICSI, Donor Sperm, Egg Donation, Egg Sharing and Surrogacy
Average desired age	No info found
Marital status	No info found
Min and Max cylces	1 cycle to 6 cycles
Number of embryos transferred	1 to 8 embryos
What are considered as	PGS with Next Generation Sequencing, Pre-implantation Generation Sequencing (PGS) , Pre-implantation genetic diagnosis (PGD), Blastocyst

advanced/ additional treatments?	culture ,IVM, Closed culture incubation (Embryoscope) ,Cyst aspiration, Trial embryo transfer,Hysteroscopy ,Transfer of sperm/eggs/embryos ,Surgical sperm aspiration ,Micro-TESE, DNA fragmentation for sperm sample, Sperm chromosome analysis, Combined DNA fragmentation and chromosome analysis, HFEA fee per cycle Sedation feee
Conditions	Not found
Exclusions	N/A

Name of the Clinic	**Advanced Reproductive Care, Inc. (ARC)**
How it assists funding?	Discounted treatment options through the nation's largest network of fertility specialists, and innovative financing programs to make fertility care affordable and accessible to more people
What are the different packages?	**ARC One-Cycle Plus** One-Cycle Plus treatment package gives 2 chances to get pregnant because the patient gets one retrieval and up to 2 embryo transfers. Services that are included in this package are based upon the usual number of office visits, ultrasounds and blood work required during an average in-vitro fertilization (IVF) cycle, with the use of frozen embryos obtained during the retrieval in this package for a total of up to 2 embryo transfers (fresh and/or frozen). Clinical care is provided following the one IVF cycle until a serum pregnancy test is performed. **ARC Two-Cycle Plus** Two-Cycle Plus treatment package gives the patient 4 chances to get pregnant because the patient gets 2 retrievals and up to 4 embryo transfers. **ARC Three-Cycle Plus** 3 Retrievals and up to 6 embryo transfers (fresh or frozen) Three-Cycle Plus treatment package gives the patient 6 chances to get pregnant because the patient gets 3 retrievals and up to 6 embryo transfers.
Average desired age	Not available.
Marital status	Not specified
Min and Max cylces	1 cycle to 3 cycles
Number of embryos transferred	2 to 6 embryos
What are considered as additional treatments?	Tubal Reversal Option Male TESA /MESA Package™ PGD/PGS Option™ Freeze-all Packages Surrogate/Gestational Carrier Packages™ Frozen Donor Egg & Donor Embryo Packages Fertility Preservation Package Genetic Testing
Conditions	Not Available
Exclusions	Not available

Name of the Clinic	**Care Fertility**
How it assists funding?	They have fixed payment plans and money back guarantee (refund) incase the treatment is not successful
What are the different packages?	IVF Unlimited Programme- 100 Percent Refund Unlimited IVF for two years Cycle monitoring in treatment Appointments during monitoring Blood work (E2, P4, LH) Cycle management Follow-up consultation post fresh cycle HFEA fee Ultrasound(s) Egg collection Follicular puncture for egg retrieval Ultrasound guidance for aspiration of ova IVF laboratory Embryo preparation for transfer Fertilisation and culture of embryo(s) Sperm preparation Time Lapse technology Embryo transfer Blastocyst culture Ultrasound guidance of embryo transfer One pregnancy ultrasound scan at six to seven weeks Freezing and storage

	Embryo freezing and one-year storage IVF Multi-Cycle Programme- (50% Refund if no success after two cycles) Fixed discounted fees that could save you 1/3 Up to 2 fresh cycles of IVF/ICSI Unlimited frozen embryo transfers Available to women under 45 using their own eggs No medical review required No refund element Donor Egg IVF Refund programme Up to two cycles of IVF including ICSI Transfer of all embryos (including unlimited frozen embryos transfers in subsequent cycles) The fertility drugs you and your chosen donor need Our EmbryoScope time-lapse technology which helps us to choose the best embryos to transfer Fixed discounted fees that could save you up to a third off the cost of treatment Freezing and one year's storage for your embryos
Average desired age	38-39 years for Unlimited plan 50 years for Donor egg IVF Refund program
Marital status	All
Min and Max cylces	Minimum 1/ 2 and Max unlimited
Number of embryos transferred	Unlimited frozen embryos transfer
What are considered as additional treatments?	Time lapse embryo imaging to monitor development of IVF embryos ❖ Blastocyst culture

Name of the Clinic	**Fertility Associates**
How it assists funding?	This fertility clinic's package gives refund of 70% of cost of programme incase of failure to get conceive.
What are the different packages?	Depending on the age of the woman, prices start from $28,600 and include drugs, ICSI, embryo storage and thawed embryo replacement. Up to 3 cycles of IVF (ICSI if required) Medication – up to 300 iu of Gonal F or Puregon per day during treatment Other standard medications used in treatment Blood tests & ultrasound scans Replacement of all frozen embryos resulting from the cycle for up to three years from the date of the final egg collection Storage of embryos up to 24 months from signing the services .. After that the patient would pay for any further storage Early pregnancy monitoring to 7 weeks gestation, including ultrasound scanning Counselling, up to 4 consultations.
Average desired age	Min age 33 and max age for this programme is 39
Marital status	Not specified
Min and Max cylces	1 to max 3 cycles
Number of embryos transferred	Unlimited embryo transfers within 3 years from the date of egg collection but number of embryos transferred per time is not specified.
What are considered as additional treatments?	Not specified
Conditions	The woman must be under 40 years old on the day of joining the programme. She should complete the programme, which may involve up to complete IVF cycles, within 18 months of signing the services agreement . The first IVF cycle must start within two months of the signing date. The patient has not had more than 2 IVF cycles previously at any fertility clinic. However, even if they have had previously a baby from IVF, they may be eligible. Review of the medical history of both the partners is mandatory. . Some medical factors may exclude applicants from this programme.(Factors not

	mentioned) The couple must be non-smokers, for at least 3 months before starting and for the duration of treatment under the programme. For Women - Hormone levels of FSH and AMH which help predict how well a woman will respond to the drugs used in IVF, BMI, Medical history are mandatorily required. For Men : Sperm quality from a semen analysis and medical history is a must.
Exclusions	❖ Diagnostic and screening tests, such as AMH, FSH, Egg Check, semen analysis, etc ❖ Any surgery ❖ Surgical sperm retrieval of sperm from the testes, if needed ❖ The use of donated eggs ❖ Assisted hatching ❖ Cost of donor sperm, including recruitment and storage fees, if needed Cost of pregnancy care after 7 weeks gestation, any hospitalisation from treatment, prenatal diagnosis and any subsequent follow-up Not all IVF treatment types will be covered.

Annexure D

Analysis of Private Insurers

Name of the Insurer	**Cigna**
Definition of Infertility	❖ Women, who are younger than 35, may want to give more time to get pregnant. ❖ Women, who are 35 or older, may want to get help soon.
Coverage	**IVF and Fertility Insurance Protection Coverage-** ❖ Prescribed drug Treatment and Laboratory Work ❖ Intracytoplasmatic sperm injection (ICSI) o IVF and ICSI may only be applied alternatively ❖ Zygote intrafallopian transfer (ZIFT) ❖ Gamete intrafallopian transfer (GIFT) ❖ Invitro fertilization (IVF) ❖ Artificial insemination (AI)
Conditions	**Not specified**
Exclusions	IVF and Fertility coverage will normally fall under a plan's Maternity Insurance Benefit and will usually be accompanied by a sub-limit specific to treatment the policyholder receives in relation to IVF and Fertility. However, it is important to note that, in some cases, the IVF and Fertility Insurance benefit may be provided through the outpatient portion of a health insurance policy; patient should ensure that he is fully aware of how this benefit operates prior to purchasing a plan. The limits on IVF and Fertility coverage will usually range from US$2,600 to US$17,000 and will normally be for the entire lifetime of the policy. This means that once the limit has been reached no more fertility or IVF treatment can be claimed for under the policy.

Name of the Insurer	**Nippon Insurance (Japan)**
Definition of Infertility	**Not specified**
Coverage	**IVF and Fertility Insurance Protection Coverage-** ❖ Prescribed drug *Treatment* and Laboratory Work ❖ Intracytoplasmatic sperm injection (ICSI) o IVF and ICSI may only be applied alternatively
Conditions	**Not specified**
Exclusions	**Not specified**

Name of the Insurer	**Kaiser Permanente**
Definition of Infertility	**Women < Age 35**
Coverage	**IVF and Fertility Insurance Protection Coverage-** ❖ in vitro fertilization (IVF) ❖ genetic services ❖ male infertility services ❖ donor sperm insemination ❖ egg donor programs ❖ gestational surrogacy
Conditions	**Not specified**
Exclusion	**Not specified**

NAME OF THE INSURANCE COMPANY	**AETNA**
DEFINITION OF INFERTILITY	Infertility is failure to conceive after 1 year of unprotected intercourse.
AGE	< less than 38
COVERAGE DETAILS	
Tests	Anti-sperm antibodies (e.g., immunobead or mixed antiglobulin method)
Diagnostic procedures	Ct or mr imaging
Non surgical treatments	Aromatase inhibitors and letrozole (femara)
Infertility surgery	Hysteroscopic adhesiolysis And many others
Assisted reproductive treatments	Ivf Ivf with embryo transfer
Additional services and artificial insemination	Gonadotropin releasing hormone (injectable medication)
Medical conditions	**Treatments permitted**
Hostile uterine cervix.	Intrauterine insemination with either husband's or donor semen (IUI-H or IUI-D)
Irreversible pathology of the fallopian tubes, resulting from an inflammatory process or from previous surgery.	In vitro fertilization and embryo transfer (IVF-ET)
When the tubes are fine and fertilization can happen in the tubes	IVF–associated techniques Gamete Intrafallopian Tube Transfer (GIFT)
Male partner has Primary germ cell failure Inheritable genetic disorder	Embryo donation
Exclusions Test exclusions	Anti-mullerian hormone

Non surgical exclusions Artificial insemination treatment exclusion Treatment related exclusions	Leukocyte immunization (immunizing the female partner with the male partner's leukocytes) Double IUI Direct Intra-Peritoneal Insemination

Annexure E

Analysis of Infertility Causes in Women

(PTO)

Sr. No	Name of the Article	Description of the study	Findings
1	Latent genital tuberculosis adversely affects the ovarian reserve in infertile women. *Kaur R Kaur T and Kaur A , 2018*	This prospective study from February 2013 to January 2016 compared 431 infertile women diagnosed with latent GTB (Group I) to 453 infertile women without latent GTB (Group II)	It was found that Latent genital tuberculosis adversely affects the ovarian reserve in infertile women. ***Genital Tuberculosis***
2	Association of Mycoplasma genitalium with infertility in North Indian women *Nonika Rajkumari, Harsimran Kaur, Amit Roy, Nalini Gupta, Lakhbir Kaur Dhaliwal, and Sunil Sethi*	A prospective observational study was conducted on 100 cases of infertile women. The control group included 100 healthy fertile women First void Urine, three endocervical swabs and enometrial biopsy samples were collected from the study group whereas only FVU and endocervical swabs were taken from the control group. .	The study shows an association of M. genitalium infection and infertility and suggests routine screening of this pathogen in patients with infertility Doctors should consider Mgenitalium infection strongly while conducting the infertility treatment tests ***M.Genitalium***
3	Association of Obesity with Hormonal Imbalance in Infertility: A Cross-Sectional Study in North Indian Women *Bhavna SethSarika Arora,Ritu Singh*	In a cross sectional study of 113 women (57 with primary infertility and 56 with secondary infertility) in the age group of 20-35 years, presenting for hormonal evaluation of infertility in a hospital	It was found that there Obesity is assocaited with harmonal derangements which are responsible for infertility ***Obesity***
4	To Study The Effect of Age And BMI on Markers of Ovarian Reserve in Indian Women with Primary Infertility of Age >35 Years *S Shukla 2016*	Fifty women with primary infertility of age >35 years having regular monthly cycles and no history of ovarian surgery were included in this cross-sectional study conducted from December 2010 until July 2011 in SMS Medical College.	FSH increases with increasing age, AMH, ovarian volume and antral follicle count decreases with increasing age FSH increases with decreasing ovarian volume and antral follicle count while s.AMH decreases with decreasing ovarian volume and antral follicle count Age has significant effect on s.AMH, s.FSH, ovarian volume

			and antral follicle count while BMI does not significantly affect these markers ***Age***
5	Prevalence of female genital tuberculosis, its risk factors and associated clinical features among the women of Andaman Islands, India: a community-based study *Parvez R, Sugunan AP, Vijayachari P, Burma SP, Mandal A, Saha MK, Shah WA.*	This study was carried during October 2011 and May 2014 in the Andaman Islands on 405 women . Endometrial specimens were collected .	Infertility and oligomenorrhoea were identified as clinical features associated with FGTB. Past history of tuberculosis and history of close contact with tuberculosis cases were identified as risk factors. ***Genital Tuberculosis***
6	Genital tuberculosis--a major pelvic factor causing infertility in Indian women. *Parikh FR, Nadkarni SG, Kamat SA, Naik N, Soonawala SB, Parikh RM.*	Three hundred women, between the ages of 25 and 35 years, with tubal factor as a cause of their infertile state at Jaslok hospital Mumbai were investigated.	49.5% had simple tubal blockage, 15.3% had tubo-ovarian masses, and 23.9% had a frozen pelvis. 75% had menstrual irregularities (indicating Endometrial involvement) ; 25.6% went through IVF procedure. The pregnancy rate after IVF-ET was 16.6% per wtransfer ***Genital Tuberculosis***
7	Polycystic ovary syndrome in globalizing India: An ecosocial perspective on an emerging lifestyle disease *Pathak G, Nichter M*	141 participants from 2012 to 2014, in Mumbai	Women's rise of lifestyle disorders linked to the impact of globalization and the pressures of "modern" identities and aspirations among middle-class populations. ***Polycystic Ovarian Syndrome/ Unhealthy lifestyle***
8	Latent celiac disease in reproductive performance of women.	. Data is collected from Department of Obstetrics and Gynecology of a tertiary teaching hospital, New Delhi. Eight hundred ninety-three women	Rates of previous preterm births, low-birth-weight infants, and cesarean section were higher in seropositive women

	Kumar A, Meena M, Begum N, Kumar N, Gupta RK, Aggarwal S, Prasad S, Batra S	(104 women with idiopathic recurrent abortion, 104 women with unexplained stillbirth, 230 cases of unexplained infertility, 150 pregnant women with idiopathic intrauterine growth restriction, 305 control cases)	compared with seronegative subjects. ***Celiac disease***
9	Longer CAG repeat length in the androgen receptor gene is associated with premature ovarian failure *Chatterjee S, Singh R, Kadam S, Maitra A, Thangaraj K, Meherji P, Modi D..*	A clinic-based case-control study. Seventy-eight patients with non-familial, non-syndromic POF, and 90 controls were recruited to investigate the CAG repeat numbers in exon 1 of the AR gene by PCR and Gene Scan analysis.	The biallelic mean CAG repeat ranged from 11 to 32 in the control women, compared to 16 to 30 in the POF patients. . Longer CAG repeat length in the androgen receptor gene is associated with premature ovarian failure ***Androgen receptor gene***
10	Adverse reproductive and child health outcomes among people living near highly toxic waste water drains in Pnjab, India *Jarnail Singh Thakur, Shankar Prinja, Dalbir Singh, Arvind Rajwanshi, Rajendra Prasad, Harjinder Kaur Parwana, Rajesh Kumar*	A cross-sectional community-based survey was conducted in which 1904 women in reproductive age group and 1762 children below 12 years of age from 35 villages in three districts of Punjab were interviewed on a semistructured schedule for systemic and general health morbidities.	Mercury, Heptachlor, chlorpyriphos, β-endosulfan, dimethoate and aldrin were found to be more than MPL (Max permissible limits) in the ground water Heavy metal and pesticide exposure may be potential risk factors for adverse reproductive outcomes. ***Reproductive toxins in Groundwater and other pollutants***
11	Are Unhygienic Practices During the Menstrual, Partum and Postpartum Periods Risk Factors for Secondary Infertility *Tazeen Saeed Ali, Neelofar Sami and Ali Khan Khuwaja*	A matched case-control study was conducted from April 2003 to March 2004. Four hundred cases were selected from five infertility clinics affiliated with tertiary-care hospitals, and 400 age-matched controls were recruited from the neighbourhood of each case. (Pakistan)	Factors found to be independently associated with secondary infertility were: previous delivery at an unclean place, delivery by a birth attendant without washing hands with soap, insertion of home-made vaginal medications, and unhygenic practices. ***Unhygienic practices during menstrual , partum and postpartum periods***
12	**Genetic association study from North India to analyze association of CYP19A1 and CYP17A1**	In a study in Punjab of total 500 women of reproductive age including 250 PCOS and 250 healthy women . Lab tests were conducted and	**It was found that that PCOS in women is a leading cause of infertility and there is an association of CYP19A1 and**

	with polycystic ovary syndrome. Kaur et al 2018	conclusions were drawn	**CYP17A1** **Polycystic ovarian syndrome/ CYP19A1**
13	Genes governing premature ovarian failure *Kumar et al 2009*	Eight hundred ninety-three women of reproductive age with idipathic recurrent abortion, unexplained stillbirth, unexaplained infertility and intrauterine growth restrictions in 2009	Variations in the Androgen receptor (Ar) gene may be one of the causes for Premature Ovarian failure in women . ***Variations in Androgen Receptor gene***
14	Metals and female reproductive toxicity. *Sengupta etal*	Endocrine disruptors alter follicle development and these chemicals are contribute to increased rates of aneuploidy, polycyctic ovarian syndrome, premature ovarian failure ,altered cyclicity and fecundity	. Altered cyclicity has been reported in Individuals who are exposed to metals and pesticides and also in women whose mothers were exposed in utero to Endocrine disruptors. Metals, as reproductive toxins, may also induce hormonal changes affecting other facets of reproductive health such as the menstrual cycle, ovulation, and fertility. ***Exposure to metals, pesticides, and whose mothers are exposed in utero to endocrine disruptors***
15	Occupational hazards Jadhav 2004		Items that can fall under the list of occupational hazards are cancer treatment drugs used by health care workers, pharmacists , Electrocnic and semi conductor workers (due to usage of ethylene glovolethes , Viscose rayon workers (Carbon disulfide) , Lead battery makers, Inonising readiation experienced by health care

			workers, dental xrays and gamma rays,and animal care workers ***Occupational hazards***
16	Women and Work *Padmini Swaminathan*	Shramshakthi report 1988	High biomass smoke levels, Women in villages work with Chulhas which have low thermal efficiency and high emission factors and it affects pregnancy outcomes adverseley. Manual Agricultural workers get exposed to pesticides, heavy manual labour , nutritional deficiencies and exposure to dust for instance by plantation workers are some of the other examples of reproductive hazards ***Biomass smoke levels, exposure to dust and pesticides, nutritional deficiency***
17	Pericentric inversion of chromosome 9 causing infertility and subsequent successful in vitro fertilization. *Muthuvel etal*	Case study on a 27 year old lady suffering from primary infertility. The woman was diagnosed with inversion of chromosome 9 .	Chromosome 9 reason for primary infertility . she concieved later with IVF (donor oocyte) ***Chromosome 9***
18	Repeated implantation f ailure versus repeated i mplantation success: dis crimination at a metabolomic level. RoyChoudhury etal	This study was conducted over a period of 10 years from 2004 to 2014 . Groups of 28 women with RIF (age ≤40 years and BMI ≤28) and 24 women with RIS (age and BMI matched) were selected from patients with primary infertility (Kolkatta) .Women with RIF had history of implanatation failure in atleast three IVF attempts (where	Valine, adipic acid, l-lysine, creatine, ornithine, glycerol, d-glucose and urea were found to be significantly down-regulated in women with RIS when compared with those with RIF, serum eNOS was found to be significantly lower in women with RIF when compared

		three high grade quality embryos were transferred during each cycle)	with RIS
19	NMR-based metabonomics for understanding the influence of dormant female genital tuberculosis on metabolism of the human endometrium. Subramani et al	Endometrial tissue samples were collected from patients reporting at the tertiary infertility care center during the period September 2011-March 2013. Women having tested positive for GTB were considered as the study group (n = 24). Normal healthy women undergoing sterilization (n = 26) and unexplained infertile women with repeated IVF failure (n = 21) volunteered to participate as controls.	In dormant GTB cases significant alterations in endometrial tissue metabolites occur, largely related to energy metabolism and amino acid biosynthesis in dormant GTB cases. Genital Tuberculosis
20	Mutations in the PTEN tumor gene and risk of endometriosis: a case-control study. ***Govatati S,***	A total of 1252 women out of which 752 had endometriosis and 500 were controls were a part of this case study which took place in from 2001 to 2009 at Institute of Reproductive Medicine (IRM), Kolkata, India; Infertility Institute and Research Centre (IIRC)	Possible involvement of the PTEN-PI3K/Akt-Bad axis in the pathogenesis of endometriosis has been found.. ***Endometriosis / PTEN-P13K /Akt-Bad axis***
21	Adrenal ganglioneuroma in	Polycystic ovarian disease (PCOD) is an endocrine disorder	Reported a rare case of adrenal ganglioneuroma in a

	a patient with polycystic ovarian disease (PCOD) : a rare association *Kumar etal*	characterised by bilateral polycystic ovaries, anovulation leading to infertility, irregular menstrual cycles and features of androgen hormone excess.	14-year-old girl with PCOD.She was referred to a Gynaecologist after detection of adrenal mass during Ultrasound. After investigation it was suggestive of ganglineauroma. This is the first of such type of case to be reported. *Adrenal Ganglioneuroma/ PCOD* . .
22	A ten year clinicopathological study of female genital tuberculosis and impact on fertility *Mondal etal*	A total number of 68 cases of gynaecological tuberculosis affecti ng different parts of female genital tract were selected	Tuberculosis involved the endometrium in 55.88%, tubes in 23.53%, ovaries in 14.71% and cervix in 5.88% of the 68 cases. 65% to 70% of the women suffering from GTB suffered from Infertility. ***Genital Tuberculosis***

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